Asia Partnership Conference of Pharmaceutical Associations (APAC)

Pharmaceutical Market & Regulatory Environment in Asia（PMRE）

ver. 2023

Volume 1: Regulatory Environment

Identification and Clarification of the Differences in Regulatory Environment between Asian Economies

APAC PMRE Task Force

April 18, 2023
Tokyo, Japan

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Abbreviation

Abbreviation	Description
ACRA	Accounting and Corporate Regulatory Authority (Singapore)
ACTD	ASEAN Common Technical Document
ADHD	Attention Deficit Hyperactivity Disorder
ADME	Absorption, Distribution, Metabolism and Excretion
ADR	Adverse Drug Reaction
AE	Adverse Event
AEFI	Adverse Event Folloing Immunization
AF	Application Form
API	Active Pharmaceutical Ingredient
ASEAN	Association of South-East Asian Nations
ASTT	Administration of Science, Technology and Training
AVG	ASEAN Variation Guideline
BA	Bioavailability
BE	Bioequivalence
BLA	Biologics License Application
BP	British Pharmacopoeia
BPOM	Badan Pengawas Obat dan Makanan (Indonesian national agency of drug and food control)
BSE	Bridging study evaluation (Taiwan)
Cat.	Category
CDE	Center for Drug Evaluation
CDFS	Council on Drug and Food Sanitation (Japan)
CDL	Central Drugs Laboratory (Kasauli)
CDRR	Center for Drug Regulation and Research (Philippines)
CDSCO	Central Drugs Standard Control Organization (India)
CEP	Certification of suitability to the monographs of the European Pharmacopoeia
CFDA	China Food and Drug Administration
CFDI	Center for Food and Drug Inspection
ChP	Chinese Pharmacopoeia
ChPC	Chinese Pharmacopoeia Commission
CIOMS	Council for International Organizations of Medical Sciences
CIRB	Centralised Institutional Review Board (Taiwan, Singapore)
CLA	Central Licensing Authority (India)
CMC	Chemistry, Manufacturing and Control
CMO	Contract Manufacturing Organization
CNIPA	China National Intellectual Property Administration
CoA/COA/CA	Certificate Of Analysis
Co-I	Co-Investigator
CoPP	Certificate of Pharmaceutical Product
COVID-19	Coronavirus Disease 2019
CPO	Contract Pharmaceutical Organization
CPP	Certificate of Pharmaceutical Product
CRC	Clinical Research Centre
CREC	Central Research Ethics Committee (Thailand)
CRF	Case Report Form
CRIS	Client Registration and Identification Service
CRM	Clinical Research Materials Notification
CRO	Contract Research Organization
CSR	Clinical Study Report
CT	Clinical Trial
CTA	Clinical Trial Application
CTA	Clinical Trial Authorization
CTA	Clinical Trial Approval
CTC	Clinical Trial Certificate
CTGTP	Cell, Tissue and Gene Therapy Products
CTD	Common Technical Document
CTIL	Clinical Trial Import License (Malaysia)
CTN	Clinical Trial Notification
CTRI	Clinical Trials Registry of India
CTW	Clinical Trial Waiver
CTX	Clinical Trial Exemption
CUHK	Chinese University of Hong Kong
CV	Curriculum Vitae
DAL	Drug Administlation Law
DAV	Drug Administration Department of Vietnam
DCA	Drug Control Authority (Malaysia)
DCGI	Drugs Controller General of India
DLP	Data Lock Point
DMC	Data Matrix Code

DMF	Drug Master File
DMR	Drug Manufacturing Regulation
DMSC	Department of Medical Sciences
DNA	Deoxyribonucleic Acid
DOH	Department of Health
DP	Drug Product
DRGD	Drug Registration Guidance Document （Malaysia）
DRR	Drug Registlation Regulations (China)
DS	Drug Substance
DSRB	Domain-Specific Review Board (Singapore)
DSUR	Development Safety Update Report
EC	Ethical/Ethics Committee
EC-MOPH	Ethics Committee - Ministry of Public Health
eCTD	Electronic Common Techinical Document
EFTA	European Free Trade Association
EMEA/EMA	European Medicines Agency
ENG	English
EP	European Pharmacopoeia
EU	European Union
FDA	Food and Drug Administration
FERCIT	Forum for Ethical Review Committees in Thailand
FP	Final Product
FRP	Facilitated Regulatory Pathway
FSC	Free Sale Certificate
G	Generic
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDA	GMP Desktop Assessment
GDA	Generic Drug Application
GDP	Good Distribution Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMP CE	GMP CErtificate
GPIN	Global Product Identification
GPP	Good Pharmacy Practice
GS1	Global Standard One
GTIN	Global Trade Item Number
GVP	Good Pharmacovigilance Practices
HA	Health Authorities
HCP	Healthcare professionals
HBRA	Human Biomedical Research Act (Singapore)
Hep C	Hepatitis C
HGR	Human Generic Resources
HGRAC	Human Genetic Resource Administration of China
HIV	Human Immunodeficiency Virus
HK	Hong Kong
HKAPI	Hong Kong Association of the Pharmaceutical Industry
HKD	Hong Kong Dollar
HKU	University of Hong Kong
HSA	Health Sciences Authority (Singapore)
IB	Investigator's Brochure
IBD	International Birthday
IC	Informed Consent
ICF	Informed Consent Form
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDR	Indonesia Rupiah
IEC	Independent Ethical Committee
IL	Import License
IMCT	International Multi-Center Clinical Trial
IMP	Investigational Medical Product
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drug
IP	Indian Pharmacopoeia
IP	Investigational Product
IPMG	International Pharmacertical Manufacturers Group (Indonesia)
IRB	Institutional Review Board
IRPMA	International Research-Based Pharmaceutical Manufacturers (Taiwan)
JP	Japanese Pharmacopoeia
JPMA	Japan Pharmaceutical Manufacturers Association

KGMP	Korea Good Manufacturing Practice
KOL	Key Opinion Leader
KOMNAS	The Indonesian Human Rights National Commission (Komnas HAM)
KP	Korean Pharmacopoeia
KPBMA	Korea Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA	Korean Research-based Pharma Industry Association
KRW	Korea Won
LoA	Letter of Authorization
LoQ	List of Questions
LPLV	Last Patient Last Visit
LTO	License to Operate
MA	Marketing Authorization
MAA	Marketing Authorization Applicant
MAH	Marketing Authorization Holder
MAV	Major Variation Application
MF	Master File (Japan)
MFDS	Ministry of Food & Drug Safety (Korea)
MFR	Manufacturer
MHLW	Ministry of Health, Labour and Welfare (Japan)
MHRA	Medicines and Healthcare Products Regulatory Agency (UK)
MIDR	Million Indonesia Rupiah
MIIT	Ministry of Industry and Information Technology (China)
MiV	Minor variation
MOH or MoH	Ministry of Health (Malaysia) (Vietnam)
MoHFW	Ministry of Health and Family Welfare (India)
MOPH	Ministry of Public Health (Thailand)
MOST	Ministry of Science and technology (China)
MRCT	Multi-Regional Clinical Trials
MREC	Medical Research & Ethics Committee (Malaysia)
MTA	Material TransferAagreement
N/A	Not Applicable
NADFC	National Agency for Drug and Food Control (Indonesia)
NATCM	National Administration of Traditional Chinese Medicine（China)
NBE	New Biological Entity
NCE	New Chemical Entity
NCO	New Combination
ND	New Delivery system
NDA	New Drug Application
NDCT	New Drugs and Clinical Trial (India)
NDOS	New Dosage form of Approved New Drug
NeeS	Non-eCTD Electronic Submission (Thailand)
NF	National Formulary
NG	New Generic
NHC	National Health Commission (China)
NHG	National Healthcare Group (Singapore)
NI	New Indication
NIBIO	National Institute of Biomedical Innovation, Health and Nutrition (Japan)
NICVB	National Institute for Control of Vaccines and Biologicals (Vietnam)
NIFDC	National Institutes for Food and Drug Control (China)
NME	New Molecular Entity
NMPA	National Medical Products Administration (China)
NMRR	National Medical Research Register (Malaysia)
NOC	No Objection Certificate
NPRA	National Pharmaceutical Regulatory Agency (Malaysia)
NR	New Route of administration
NS	New Strength of Approved New Drug
NSAE	Non Serious Adverse Event
NUHS	National University Health System (Singapore)
ODD	Orphan Drug Designation (Taiwan)
OECD	Organisation for Economic Cooperation and Development
OPPI	The Organisation of Pharmaceutical Producers of India
OTC	Over-The-Counter
PBRER	Periodic Benefit Risk Evaluation Report
PD	Pharmacodynamics
PG	Pharma Group (Vietnam)
PhAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PhIRDA	China Pharmaceutical Innovation and Research Development Association
PhP	Philippine Peso
PHREB	Philippine Health Research Ethics Board
PI	Package Insert

PI	Principal Investigator
PIC/S or PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIL	Patient Information Leaflet
PK	Pharmacokinetics
PMD Act	Pharmaceuticals, Medical Devices and Other Therapeutic Products Act （Japan)
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMF	Plant Master File
PMS	Post-Marketing Surveillance/Study
PNDF	Philippine National Drug Furmulary
PReMA	Pharmaceutical Research and Manufacturers Association (Thailand)
PRH	Product Registration Holders (Malaysia)
PSAR	Pandemic Special Access Route (Singapore)
PSM	Pre-submission Meeting (Malaysia)
PSUR	Periodic Safety Update Report
PV	Process Validation
PvPI	Pharmacovigilance Program of India
QC	Quality Control
QOS	Quality Overall Summary
QP	Qualified Person
QR	Quick Response
R&D	Research and Development
RC	Registration Certificate
r-DNA	recombinant DNA
RDPAC	R&D-based Pharmaceutical Association Committee
REMS	Risk Evaluation and Mitigation Strategy
RFID	Radio Frequency Identification
RMP	Risk Management Plan
RNA	Ribonucleic Acid
RRC	Research Review Committee
RTF	Refuse-To-File (Taiwan)
RWE	Real-World Evidence
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SAKIGAKE	"Breakthrough Therapy"-type priority review system (Japan)
SAMR	State Administration for Market Regulation (China)
SAPI	Singapore Association of Pharmaceutical Industries
SARS-CoV-2	Severe Acute Respiratory Syndrome COronaVirus 2
SAS	Special Access Scheme
SEC	Subject Expert Committee
SGD	Singapore Dollars
SMF	Site Master File
SMP	Safety Monitoring Program (Thailand)
SMPC/SmPC	Summary Product Characteristics
sNDA	supplemental New Drug Application
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authorities
SSR	Site Summary Report
SUSAR	Suspected Unexpected Serious Adverse Reaction
TCTC	Taiwan Clinical Trial Consortium
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration (Australia）
Thai-FDA	Thailand Food and Drug Administration
THB	Thai Baht
TP	Therapeutic Products
TPI	Taiwan Package Insert
USA	United States of America
USADRs	Unexpected Serious Adverse Drug Reactions
USD	United States Dollar
USFDA	US Food and Drug Administration
USP	United States Pharmacopoeia
VN	Vietnam
VNM	Vietnamese
WD	Working Day
WHO	World Health Organization
XDR TB	eXtensively Drug-Resistant TuBerculosis

EXECUTIVE SUMMARY

China | RDPAC/PhIRDA

General Information Related to China Regulatory Environment

1. Notice of State Administration for Market Regulation Notice on Issuing Legislative Work Plan 2022

Link: https://gkml.samr.gov.cn/nsjg/fgs/202204/t20220427_344262.html

2. The 2021 Drug Review Annual Report

Link: https://www.cde.org.cn/main/news/viewInfoCommon/f92b7bdf775bbf4c4dc3a762f343cdc8

3. CDE Notice on Annual Report on the Current Status of Clinical Trials for New Drug Registration in China (2021)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/1839a2c931e1ed43eb4cc7049e189cb0

4. 2021 Annual Report on Drug Inspection by Center for Food and Drug Inspection of NMPA

Link: http://cfdi.org.cn/resource/news/14698.html

Drug Review and Approval Regulations and Policy

5. NMPA Notice of National Medical Products Administration on the Issuance of Administrative Provisions on Annual Reports for Drugs

Link: https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20220412172455115.html?type=pc&m=

6. NMPA Notice on the Issuance of Two Informatization Standards, including the “Identification Specification of Drug Traceability Code” (No. 50 in 2022)

Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20220627170840162.html

7. NMPA Notice on Rules for the Administration of Vaccine Manufacturing and Distribution (No.55 in 2022)

Link: https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20220708185734126.html?type=pc&m=

8. Measures for the Administration and Supervision of Drug Online Sale

Link: https://gkml.samr.gov.cn/nsjg/fgs/202209/t20220901_349742.html

9. NMPA Notice on Provisions on the Administration of Drug Recalls (No.92 in 2022)

Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20221026164304199.html?type=pc&m=

10. NMPA Notice on Investigational Drugs (Pilot for Implementation)

Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20220527182006196.html?type=pc&m=

Drug Registration Related Regulation and Working Documents

11. Announcement on Implementing Electronic Application of Drug Registration (2022, No. 110)

Link: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20221130190751164.html

12. CDE Notice on Drug Registration Electronic Submission Related Requirements

Link: https://www.cde.org.cn/main/news/viewInfoCommon/4b75cceb52914fbfe55f5214d93b804b

13. NMPA Announcement by the National Medical Products Administration on Issuing Electronic Drug Registration Certificates (No.83 in 2022)

Link: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/ggtg/qtggtg/20221009195621184.html

14. NMPA Announcement on Enabling the Electronic Certificate for Lot Release of Biological Products and Electronic Approval Letter for Project Approval of Experimental Study of Narcotic Drugs and Psychotropic Drugs (No.84 in 2022)

Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20221011170846123.html?type=pc&m=

15. CDE Notice on Drug Evaluation on Issuing Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Implementation) (No.54 in 2021)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/c1dd9f7df30d686a2adab91f7f34587e

16. CFDI Notice on five documents, including Working Procedure of Drug Registration Inspection (for Trial Implementation) (No.30 in 2021)

Link: https://www.cfdi.org.cn/resource/news/14200.html

17. CDE Notice on Adjustment of Acceptance Working Methods and Requirements for Acceptance of Application Dossiers during the Epidemic

Link: https://www.cde.org.cn/main/news/viewInfoCommon/4e0290d92779161afe20e6ae8e934a65

18. NMPA Announcement on Provisionally Extending the Time Limit for Supplementary Dossiers for Drug Registration Application (No.86 in 2022)

Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20221014162059113.html?type=pc&m=

19. Notice of the Center for Drug Evaluation of the National Medical Products Administration on Issuing the Working Procedures for Changes during the Review of Drug Registration Application (Trial) (YSY [2022] No. 597)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/0d5a8825b3da3461f93de60674100111

20. CDE Notice on Management Practice for Suspension and Resumption of the Evaluation Timing in the Evaluation Process of National Medical Products Administration (Trial) (YSY [2022] No. 614)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/f209bd2544934ad27704b7efa3f61a4f

21. Submission Dossier and Requirements for Rx Switch to OTC

Link: https://www.cdr-adr.org.cn/tzgg_home/202209/t20220930_49842.html

22. Notice on the Improvement of National Drug Standards in 2022

Link: https://www.chp.org.cn/gjyjw/tz/16975.jhtml

Human Generic Resources (HGR)

23. Notice on Updating Frequently Asked Questions on Human Genetic Resources Administration

Link: https://www.most.gov.cn/tztg/202203/t20220304_179634.html

24. Notice on Updating Frequently Asked Questions on Human Genetic Resources Administration (Q&A Series II)

Link: https://www.most.gov.cn/tztg/202204/t20220415_180263.html

Special Drug Policy

25. NMPA Notice on <Implementation Plan Supporting for the Manufacture of Drugs by Drug Marketing Authorization Holders from Hong Kong and Macao in 9 Mainland Cities in GBA> and <Implementation Plan Supporting for the Production of Medical Devices by Medical Devices Registrant from Hong Kong and Macao in 9 Mainland Cities in GBA>

Link: https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjzh/20220629171101193.html?type=pc&m=

26. NMPA Notice on <Work Plan for Temporary Import of Drugs Urgently Needed in Clinical Practice> and <Work Plan for Temporary Import of Clobazam>

Link: https://www.nmpa.gov.cn/xxgk/fgwj/qita/20220628165440148.html?type=pc&m=&GXMEUwefOdZn=1672148867515

27. Center for Drug Evaluation, NMPA Hainan Medical Products Administration Hainan Boao Lecheng International Medical Tourism Pilot Zone Administration Measures for the Implementation of Real-world Study of Drugs (No.41 in 2022)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/c80d3570a2fe0eab698cc0e3e9666174

General R&D Guidelines

28. CDE Notice on Technical Guideline on the Preparation of Reference Safety Information in an Investigator’s Brochure (No.60 in 2021)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/7a46f5d526a64bb53c53e50c6afb9215

29. CDE Notice on Guidelines for the Application of Patient-reported Outcomes in Drug Clinical Research (For Trial Implementation) (No.62 in 2021)

Link: https://www.cde.org.cn/main/news/viewInfoCommon/c2f79c22e8678241b030c71523eb300c

30. CDE Notice on Technical Guidelines for Food-Effect Studies in the Development of New Drugs (No.64 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/4f21fc720672cf26ad0efbe0207fdced
31. CDE Notice on Guidelines for the Preparation of Clinical Risk Management Plan (Trial) (No.68 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/77e34e30c7141b2770ddd6f80e80f9ff
32. CDE Notice on Technical Guideline for Pharmacokinetic Studies in Patients with Impaired Renal Function (Trial) (No.69 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/c8a93c12537f5e8a624e57bbfd80f2bd
33. CDE Notice on Guidelines for Drug Clinical Trial Design for the Prevention of Nausea and Vomiting Caused by Antineoplastic Drugs (Trial) (No.70 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/2e26d1a47cb40eea7976702d209f54a3
34. CDE Notice on Technical Guidelines for Drug Non-clinical Dependence Study (No.2 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/3aa4564491cd73c5e581dd228c8aee34
35. CDE Notice on Technical Guidelines for Bioavailability and Bioequivalence Study of Innovative Drugs in Human (No.4 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/34d91794def0eed2bb15c48ac496c76a
36. CDE Notice on Technical Guidelines for Clinical Pharmacokinetic Study of Modified-release Preparations in Modified New Drugs (No.3 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/a7b81292e7c15e331ece179580019112
37. CDE Notice on Technical Guidelines for Clinical Studies of Dependence (Trial)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/0a9af3d03d861df5b876d8343d917314
38. Announcement of the Center for Drug Evaluation of the National Medical Products Administration on Issuing the Guidelines for General Considerations for Organizing Patient Participation in Drug Development (Trial) (No.46 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/41c7a683e4d0dcca28bccadc47096d2a
39. CDE Notice on Guidelines for Drug Clinical Trial Data Management and Statistical Analysis Plan (No.63 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/825fc74efe0a1c699eb8a1f02118e88e
40. CDE Notice on Guidelines for Randomization in Drug Clinical Trials (Trial) (No.5 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/402c511b46bfa8c472fd6aad6e164557
41. CDE Notice on Statistical Guideline for Centralized Monitoring of Drug Clinical Trials (Trial) (No.11 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/0a0ebbd5d09ec9fe6fcdc6e76d526314

CDE Guidelines for Specific Therapeutic Areas, Indications and Delivery Route
42. CDE Notice on Technical Guideline on the Clinical Trials of Drugs for Treatment of Crohn's Disease (No.65 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/2d62a1be479a74bbc6e649e6e05d6f14
43. CDE Notice on Technical Guidelines for Clinical Trials of Therapeutic Drugs for Ulcerative Colitis (No.66 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/c080c9172c57a118746020aa7e2d96d5
44. CDE Notice on Technical Guideline on Clinical Trials of Direct-Acting Antiviral Drugs for Chronic Hepatitis C (No.67 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/010fcf987af9610ac7a8e992a128e295
45. CDE Notice on Technical Guidelines for Clinical Trials of New Anti-rabies Virus Monoclonal Antibody Drugs (No.6 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/b2e689613ea048acacaf509b658b3b9f
46. CDE Notice on Technical Guidelines for Clinical Trials of Drugs for the Treatment of Arterial Pulmonary Hypertension (No.7 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/33fcebca87d9142d59173d4e96ca5955
47. CDE Notice on Technical Guideline for Clinical Trials of Drugs for the Treatment of Pediatric Pulmonary Arterial Hypertension (No.8 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/eb048d5c509f06e705e84e49a3434423
48. CDE Notice on Technical Guideline on Clinical Risk Management Plan of Biologics License Application for Cell Therapy Products of Chimeric Antigen Receptor-T (CAR-T) (No.15 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/574e71202540d2b38cf34dfeb5673a86
49. CDE Notice on Technical Guidelines for Clinical Trials of Locally Applied and Locally Acting Drugs (No.32 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/f993bea8924aff71b361ad907612dbcd
50. CDE Notice on Technical Guideline for Flavor Design and Evaluation of Pediatric Drugs (Trial Implementation) (No.37 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/35fa15bba5721b0c653262d14792f3b6
51. CDE Notice on TECHNICAL GUIDELINES FOR CLINICAL DEVELOPMENT OF BISPECIFIC ANTINEOPLASTIC AGENTS (No.40 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/e9e97adf7fd91fff6c49afac1320d233

CDE Guidelines for Cell and Gene Therapy Drugs
52. CDE Notice on Technical Guidelines for the Pharmaceutical Study and Evaluation of Ex vivo gene Modification System (Trial) (No.29 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/6f14372f020446361601bb074a09410d
53. CDE Notice on Guideline for Chemistry, Manufacturing, and Control (CMC) Studies and Evaluation of Immune Cell Therapy Products (Trial) (No.30 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/0584963a84e01bb4d83022f559d22144
54. CDE Notice on Technical Guidelines for the Pharmaceutical Study and Evaluation of in Vivo Gene Therapy Products (Trial) (No.31 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/c0ec5e347ba84df67bf75e15f6ad3f3f
55. CFDI Notice on Guidelines for Production Quality Management of Cell Therapy Products (Trial) (No.4 in 2022)
Link: https://www.cfdi.org.cn/resource/news/14938.html

CDE Guidelines for Rare Disease
56. CDE Notice on Technical Guidelines for Clinical Drug Development for Rare Diseases (No.71 in 2021)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/c4e1ef312a0a0c039a7a4ca55b91d4e8
57. CDE Notice on Statistical Guidelines for Clinical Research on Rare Disease Drugs (Trial) (No.33 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/058e0d665b785e79b7f4f24dc1dc970c

CDE Guidelines for Variation
58. CDE Notice on Technical Guidelines for Protocol Changes during Drug Clinical Trials (Interim) (No.34 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/c9d649a44ba90b52ceb8072c28da768f
59. CDE Notice on Questions & Answers Regarding Dissolution Curve Study Conditions in the Technical Guideline on Studies of Post-marketing Pharmaceutical Changes to Chemical Drugs (Interim) (No.39 in 2022)
Link: https://www.cde.org.cn/main/news/viewInfoCommon/d908679d78f7c7d04179831b5f4390d3

Guidelines for Drug-device Combination Product
60. NMPA Notice on Two Guidelines for Registration Review Including the Guidelines for Registration Review of Drug-device Combination Products Mainly Acting as Medical devices (No.3 in 2022)

		Link: https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20220117145645132.html?type=pc&m=&GXMEUwefOdZn=1672147689272 61. CMDE Notice on Guidelines for the Registration and Review of Clinical Trials of Original Companion Diagnostic Reagents Developed Simultaneously with Anti-Tumor Drugs (No.28 in 2022) Link: https://www.cmde.org.cn/xwdt/zxyw/20220628135504141.html Guidelines for Pharmacovigilance 62. Notice on Issuing the Guideline for the Preparation of the Pharmacovigilance System Master File Link: https://www.cdr-adr.org.cn/drug_1/zcfg_1/zcfg_zdyz/202202/t20220228_49518.html 63. NMPA Notice on Issuing the Pharmacovigilance Inspection Guidelines Link: https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjyp/20220415102743184.html?type=pc&m= 64. CDE Notice on Issuing Guideline on the Adverse Drug Reaction Data Summary of Anti-tumor Drug Package Insert (No.23 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/ba1a3e96f3ab0dc18a18416be7345f2f 65. Guideline on MedDRA coding for Marketing Authorization Holder Link: https://www.cdr-adr.org.cn/drug_1/zcfg_1/zcfg_zdyz/202205/t20220506_49658.html 66. CDE Notice on Technical Guidelines for the Evaluation of Immune-Related Adverse Events of Antitumor Therapy (No.25 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/4c099404406a69e176c2812cb85bea91 CDE Guidelines for Generic Drugs 67. CDE Notice on Technical Guidelines for Crystal Research of Chemical Generic Drugs (Trial) (No.61 in 2021) Link: https://www.cde.org.cn/main/news/viewInfoCommon/0865981f43397249e373ee6d6e5bd66b 68. CDE Notice on "Trials of Questions and Answers on the "Technical Guidelines for Human Bioequivalence Research of Chemical Generic Drugs with Pharmacokinetic Parameters as Endpoint Evaluation Indicators" concerning the "formula ratio similarity" of the multi-strength exemption of BE pharmaceutical evaluation standard (No. 16,2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/d4b0c931e393e5a803d77ddc31383008 69. CDE Notice on Technical guidelines for the clinical pharmacological study of biosimilar drugs (No.17 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/58b06d54af4f19d02a17e4d4d8d374f7 70. CDE Notice on Technical Guidelines for Pharmaceutical Research and Evaluation on Biosimilars of Insulin Products (No.22 in 2022)" Link: https://www.cde.org.cn/main/news/viewInfoCommon/14fe0217047454f6da511a05881dba6d 71. CDE Notice on Technical Guidelines for Bioequivalence Studies of Aspirin Enteric-coated Tablets Link: https://www.cde.org.cn/main/news/viewInfoCommon/8fb67c2a70d425073f8b8618bde38d2c CDE Guidelines for others 72. CDE Notice on Technical Guideline on Powder Mix Uniformity and In-process Dosage Unit Uniformity Studies for Oral Solid Chemical Drugs (Trial) (No.19 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/ddc61dacf5e355d67f780f5202dde110 73. CDE Notice on Issuing the Common Format and Compiling Guidance for the Package Insert of Chemical Drugs and Biological Products (No.28 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/f181ed96619e3bef4ce8154bb66d91bb COVID-19 74. CDE Notice on the Technical Guidelines for Clinical Trials of New Antiviral Drugs for COVID-19 (Trial) (No.18 in 2022) Link: https://www.cde.org.cn/main/news/viewInfoCommon/2145939b5256cc7a210c2c7830598da2
Hong Kong	HKAPI	Update of list of reference countries for registration of Pharmaceutical Products was issued and effective on the 1st of November 2022 to extend the acceptance of new Stringent Regulatory Authority (SRA) reference country approvals for new drug application
India	OPPI	No major updates are provided.
Indonesia	IPMG	●BPOM issued some new regulations, such as BPOM Regulation No. 22 Year 2022 regarding 2D Barcode (enacted on Oct 5, 2022), No. 15 Year 2022 regarding Pharmacovigilance Implementation (enacted on Jul 7, 2022), No. 30 Year 2022 regarding Import of Drugs and Drug Materials through the Special Access Scheme (enacted on Nov 24, 2022), No. 26 Year 2022 regarding Control of the Importation of Drug and Food Materials into Indonesian Territory (enacted on Nov 14, 2022), No. 27 Year 2022 regarding Control of the Importation of Drugs and Food into Indonesian Territory (enacted on Nov 14, 2022). ●Several draft regulations also being discussed, such as BPOM regulation on Clinical trial approval, Drug registration guideline ●BPOM and Ministry of Health took necessary actions for responding Ethylene Glycol and Diethylene Glycol contamination issue in Indonesia.
Japan	JPMA	Since September 2022, the revised PMD Act. regarding clinical trial notification and clinical trial adverse event report has been fully enforced.
Korea	KPBMA/KRPIA	"Regulation on the Renewal of Drug Products" was revised to precisely define the documents to be submitted GMP inspections for foreign manufactures are conducted in one of the two methods: on-site inspection and remote assessment.
Malaysia	PhAMA	The Drug Registration Guidance Document Third Edition Fourth Revision was updated in January 2023 with 33 Appendices. https://npra.gov.my/easyarticles/images/users/1047/DRGD%20Jan%202023/Complete-Drug-Registration-Guidance-Document-DRGD-3rd-Edition-4th-Revision-January-2023.pdf The Malaysia Variation Guideline for Pharmaceutical Products 2nd Edition was published in July 2022 with key changes in timelines for variation application review and variation approval implementation. https://www.npra.gov.my/easyarticles/images/users/1131/Malaysian-Variation-Guideline-for-Pharmaceutical-Products-2nd-Edition-July-2022.pdf NPRA has been active leading the regional joint assessment procedure and successfully published the latest ASEAN Joint Assessment Procedure for Pharmaceutical Products and ASEAN Priority Disease List on its website in April 2022 to reflect improvements in process and timeline. https://www.npra.gov.my/index.php/en/directive-general/1527125-asean-joint-assessment-procedure-for-pharmaceutical-products-public-announcement.html The first Malaysia Guideline on E-labelling has been drafted by the Ministry of Health-Industry task force and is expected to be tabled and endorsed by the Malaysia Drug Control Authority (DCA) in early 2023. Work is also in progress for finalization of the Malaysia Guideline for Nitrosamine and Impurities. NPRA is expected to continue with initiatives to strengthen reliance, collaboration and digitalization.
Philippines	PHAP	Lessons from the pandemic continue to influence the reforms instituted by FDA. More apparent is the introduction of reliance-based pathways for drug registration called the Facilitated Review Pathways and the WHO Collaborative Registration Procedure which facilitates the processing to as early as 60 days. FDA is also starting its review and revision of the Drug Registration Guidelines – which has been the prevailing system since 1989.
Singapore	SAPI	HSA launched several key initiatives: 1) Enhancing regulatory efficiency through reliance mechanism: - Dossier clarification supplement: Appendix 18A introduced in 2018 was extended to NDA biologics, and updated to included specifics on DS and DP.specifications, container closure systems and shelf life. - Singapore signature into Hague convention, thereby allowing apostillation in place of the previous notarization legalization requirement – reflected in HSA TP guidance update Jun 2022. - Expansion of ACCESS work-sharing initiative to include UK MHRA, thereafter experienced 2 5-way ACCESS procedures in 2022. Introduction of GMP reliance position and Clinical Trial working group in 2022, in-line with the ACCESS Strategic plan 2022-2024.

		2) Enhancing regulatory clarity and tools for industry self-guide - Online Self-Guided Tool for MiV - Online FAQ 3) Enhancing regulatory clarity and tools for industry self-help - Clarity in submission requirements 4) Final guidance on e-labelling published in April 2021 5) Introduction of pre-submission meeting procedures and providing clarity on NDA submission process - New addition in HSA TP guidance update Aug 2022
Taiwan	IRPMA	No major updates are provided.
Thailand	PReMA	Thai FDA has a major regulatory reform starting from 15 February 2023. Product Registration: renewal product is required to convert to e-CTD or Non-eCTD Electronic Submission (NeeS) before renewal. GMP clearance: change to "by-site" instead of "by-product". Advertisement to HCP: auto-approval process. Variation: notifications like auto-approval. Clinical Trial related activity: Overall requirement does not alter from 2022 but about to reforming from manual submission to electronic submission depending on implementation plan from Thai FDA.
Vietnam	PG	The MOH issued Circular 08/2022/TT-BYT which replaced Circular 32/2018/TT-BYT. In a welcoming development, Vietnam's CPP requirement now follows the WHO template. The concept of reference regulatory body based on the recommendation of the EU is removed and the concept of the European Medicines Agency (EMA) and the Stringent Drug Regulatory Authority (SRA) according to WHO classification is adopted. Circular 12/2022/TT-BYT Amendments to some Articles of the Circular No. 35/2018/TT-BYT was also came into effect in early January 2023. On the other hand, several major key legislations, namely Pharma Law and Decree 54/2017, are also being revised with the aim to make the pharmaceutical sector more sustainable, predictable with simplified procedures suitable with international practice.

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IND/CTA	Requirements to be the IND/CTA applicant	Sponsor (Companies) or regulatory agency (CRO) or institute	CRO or doctors who can follow standards of GCP.	Any person, a company or an institution or an organization responsible for initiation and management of a clinical trial or their representative can be IND/CTA Applicant Ref: New Drugs and Clinical Trial Rules, 2019 [Gazette Notification G.S.R 227(E)]	CRO, Companies and doctors who can follow standards of GCP.	GCP applies to clinical trials conducted by companies and investigators. CROs are able to submit the Clinical Trial Notification (CTN) if they serve as the in-country caretaker.	The company or CRO, etc. who are registered in Korea	An investigator, or an authorised person from a locally registered pharmaceutical company/ sponsor/ Contract Research Organisation (CRO) with a permanent address in Malaysia can make the application. [Malaysian Guideline for Application of Clinical Trial Import Licence (CTIL) and Clinical Trial Exemption (CTX) §4.1] Notes: Applications for CTIL/CTX containing "poison/drug" should be made by Poison License Type A Holder in a private sector or Annual Retention Certificate Holder by public pharmacist. The holder of CTIL/CTX for a particular product does not need to conduct the clinical trial himself/herself.	FDA-licensed Sponsors and Contract Research Organizations (CROs) A license to operate (LTO) is required for a CRO and its Sponsor, prior to the conduct of clinical trial. (Administrative Order No. 2020-0017)	CRO is possible, however the sponsor should be a locally registered business entity registered with the Accounting and Corporate Regulatory Authority (ACRA) in Singapore. In order for the sponsor to carry out electronic transactions with HSA on the sponsor company's behalf, the sponsor should apply for a Client Registration and Identification Service (CRIS) account to access PRISM.	The applicant is the pharmaceutical license owner or local legal entity with sponsor's delegation in Taiwan. CRO can be an applicant if the company also has been registered as a pharmaceutical company in Taiwan.	Drug manufacturing/import license holder or government (applicant can be sponsor or CRO)	Sponsor companies, CROs and doctors who can follow GCP standards CPO or CRO
	Clinical trial consultation system If consultation system exists, input "yes" and describe the details such as consultation timing or procedures.	Yes During R&D process, communication and consultation can be conducted for traditional Chinese medicines, chemical medicines and biological products, including Type I (the meeting held on the purpose to address the major safety issues encountered during the clinical trials of drugs, and the major technical issues in the R&D process of the breakthrough therapeutic drugs), Type II(pre-IND meeting, meeting at the end of Phase II/pre-clinical meeting of Phase III), and Type III (all meeting aside from Type I and Type II). For detailed requirements, may refer to Measures for Administration of Communication for Drug R&D Activities and Technical Review (No.48 of 2020) and NMPA Announcement of China National Drug Administration on Adjusting Review and Approval Procedures for Drug Clinical Trial (No. 50 of 2018).	No	Yes, the consultation approach is defined Pre-submission meeting in NDCT Rules: (1) Any person who intends to make an application for grant of license or permission for import or manufacture of new drugs or to conduct clinical trial may, request by making an application in writing, for a pre-submission meeting with the Central Licensing Authority or any other officer authorized by the Central Licensing Authority for seeking guidance about the requirements of law and procedure of such license or permission of manufacturing process, clinical trial and other requirements. (2) The application for pre-submission meeting under sub-rule (1) may be accompanied by particulars and documents referred to in the Second Schedule, as available with the applicant to support his proposal along with fee as specified in the Sixth Schedule. (3) Where the applicant intends to seek guidance about the sale process of new drugs or import license, in addition to the purposes referred to in sub-rule (2), the fee as specified in the Sixth Schedule shall be submitted along with the application. (4) Where the Central Licensing Authority is satisfied that the application is incomplete or the information or the documents submitted along with the same are inadequate, they may within a period of thirty days from the receipt of the same, intimate the facts to the applicant in writing and direct him to furnish such further information or documents as are necessary in accordance with the provisions of the Act and these rules. (5) In the pre-submission meeting, the Central Licensing Authority or any other person authorized by it shall provide suitable clarification to the applicant. Ref: Rule 98 - New Drugs and Clinical Trial Rules, 2019 [Gazette Notification G.S.R 227(E) dated March 19, 2019]	Yes The consultation with Head of evaluator & Assistant Director by email and appointment before discussed.	Yes Various clinical trial consultations are offered by PMDA on new drugs and biological products (e.g., pre-PhI/ Pre-PhIIa/Pre-PhIIb/End of PhII study, Pre-application, Quality, Safety, etc.).	Yes Pre-IND/CTA consultations are offered by IND/CTA applicants throughout medical product development phases of chemical and biological products. The primary review opinions will be returned or face-to-face meeting instead of the review opinion can be will be held within 20 days after pre-IND consultation requests. The IND/CTA applicants can also request the face-to-face meeting. The final review opinions will be returned within 30 working days after application by MFDS if there isn't any argument.	Yes NPRA has issued the Guidance Document for Pre-Submission Meeting (PSM) First Edition (February 2020). The main objective of PSM is to provide regulatory advice (with regards to quality, safety and efficacy aspects) to applicants prior to the submission of an application to register a product. Scope of product categories: - New chemical entities - Biologics including biosimilars - Natural products with therapeutic claim - Health supplement products with disease risk reduction claim	Yes Consultation is done through official letters. Currently, there is no provision for face-to-face consultation with FDA.	No, but company can always write in to HSA to request for a meeting.	Yes Regulation consultation service is available for all phases of product development. In 2018 the reasonable consultation fee will be charged to the applicant and the consultation result would be recognized as formal record during NDA review. For more detailed information, please refer to the following website. http://www.cde.org.tw/eng/consultation_services/assistance_explain?id=14	Yes Can consult at FDA (Such as direct contact, telephone)	No There is no official consultation in place; however, sponsors can send letters to the Administration of Science Technology and Training under the Ministry of Health in order to request consultation.

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
IND/CTA	Flow of clinical trial notification, IND application and IRB permission	· Communication and exchange meeting for new drugs can be applied before 1st IND submission in principle, except some special conditions which listed in the guidance of No.48 of 2020. · No mandatory requirement to complete IRB review prior IND submission · IRB review should have been completed before clinical trial started. · When IND submission accepted by CDE, if no comments from CDE within 60 WD, clinical trial can be started.	Parallel submission to Department of Health and Ethics Committee. Both approvals needed.	Clinical trial on new drug shall be initiated after approval by CDSCO in Form CT-06 (NOC: No Objection Certificate from DCGI) after positive opinion from Subject Expert Committee (SEC) or by IND Committee in case of IND application and approval of respective Institutional/Independent Ethics Committee (EC). In case of parallel applications, CDCSO & respective EC will grant conditional approval and note that the trial should only start after CDSCO and EC approval.	Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval, annex II and annex III	A clinical trial is conducted based on the notification, and not based on an application. Contracts with clinical sites should be signed after 30 days from the date of clinical trial notification (14 days from the second trial onwards).	IRB approval is required before or after MFDS approval. In addition, parallel application is allowed. Clinical trials can be initiated after both of MFDS and IRB approvals.	A CTIL from the Drug Control Authority (DCA) authorising the licensee to import a product for purposes of clinical trials is required. All the clinical trials that require CTIL/ CTX must be registered with NMRR (National Medical Research Register). NPRA will only accept favorable opinion/ approval issued by EC that is registered with the DCA. [Malaysia Guideline for Application of CTIL and CTX §5.1 and S5.2]. Note: The process flow also includes First-In-Human Clinical Trials (S5.2).	In March 2020, FDA issued a streamlined process in obtaining approval for Clinical trials. The process begins with the screening of application by FDA for completeness. If accepted, FDA forwards it simultaneously to Regulatory Reviewers and the Scientific Advisory Committee; FDA makes the final decision based on their recommendations. Ethical review approval is not a prerequisite for FDA application, and may be done in parallel with FDA review. (Administrative Order No. 2020-0010)	Under the Health Products Act and its subsidiary legislation, the Health Products (Clinical Trials) Regulations, and require either Clinical Trial Authorization (CTA) or acceptance of Clinical Trial Notification (CTN) prior to initiation of the clinical trial. There are three clinical trial submission routes (CTC, CTA and CTN) Clinical trials of therapeutic products (e.g. pharmaceutical drugs and biologics) require Clinical Trial Authorization (CTA) or acceptance of Clinical Trial Notification (CTN) before the trial can be initiated or conducted. Such clinical trials must be conducted in compliance with the Health Products (Clinical Trials) Regulations and the ICH E6 Good Clinical Practice guidelines. Clinical trials of medicinal products (e.g. cell, tissue and gene therapy products or complementary health products) require a Clinical Trial Certificate (CTC) before the trial can be initiated or conducted. Such clinical trials must be conducted in compliance with the Medicines (Clinical Trials) Regulations and ICH E6 Good Clinical Practice guidelines. For clinical trials that require Clinical Trial Authorization (CTA) or a Clinical Trial Certificate (CTC), the clinical trial application may be submitted concurrently to HSA and the relevant IRB. For clinical trials that require Clinical Trial Notification (CTN) to HSA, the submission should be made only after having received IRB approval for the clinical trial.	IRB submission in parallel with TFDA's review of an IND application and c-IRB (jointed IRB review) system has been adopted since 2013.	Same as 2021 defined in Notification of Thai FDA Re: Regulations on Import or Order the drug into the Kingdom for Clinical Research on 31 May 2018 Submission fee applied: rate as of 24 Dec 2018 (not change) Initial review fee: 1,000 THB Expert review fee: 4,000 THB Consultant fee: 2,000 THB	In short: Clinical trial notification, then Hospital IRB permission, IND application and MOH IRB approval. Clinical trial should be submitted to Site level first. After receiving IRB/EC approval at site level (For some Hospitals under Department of Health, the hospital should get approval from MOH and People's Committee before submitting it to HA), we can continue submission to health authority (HA). The CT can be initiated after getting HA's, in this case the Ministry of Health's, approval. Import License (IL) in only obtained after having HA approval.

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IND/CTA	Time required for clinical trial notification, IND application and IRB permission obtainment Official timeline (working days) if it is announced.	Implied permission system for clinical trial: -If no comments from CDE since IND submission accepted in 60WDs, clinical trial can be started. -If any queries from CDE, response should be submitted within 5WDs. Otherwise, another round of 60WDs is needed.	120 calendar days.	CT- of a ND or IND review- 90 days (as per New Drugs & Clinical Trial Rules, 2019) CT of a ND or IND as part of discovery, research ad manufacture in India – 30 days or else seemed approval. (as per New Drugs & Clinical Trial Rules, 2019) EC review – 14 to 60 days (depending on the Institutional EC meetings timelines, industry experience)	Timeline for evaluation is 20 working days for protocol & amendment of clinical trial after NADFC stated the protocol & amendment complete	The “after 30 days from the first clinical trial notification ” rule applies for drugs containing new active ingredients , new ethical combinatio n drugs and drugs with a new administrat ive route. Clinical trials can be started 14-days after the clinical trial notification from the second trial onwards (for the same product).	In principle, the review of an IND application takes 30 working days. Queries can be given by MFDS up to 2 times. In case of queries given, it would take 2-3 months or more. -The deadline for answering first queries is basically 30 calendar days and can be extended up to 2 times if there are proper reasons.(the deadline is 30 calendar days at a time). -The deadline for answering second queries is 10 calendar days IND approval by MFDS and IRB review can be got in parallel. Based on individual application (level of document), the requirements of query, expected period and additional document can vary.	Official Timeline for CTIL/CTX: Normal: *45 working days: For Phase 1 including First-In-Human Clinical Trials, biologicals, biotechnology, cell and gene therapy products, herbal/natural products with therapeutic claim 30 working days: For Products other than mentioned above **Fast Track: 22 working days: For Phase 1, biological, biotechnology, cell and gene therapy products, herbal/natural products with therapeutic claim 14 working days: For Products other than mentioned above. Malaysia Guideline for Application of CTIL and CTX §5.3]. The IRB/IEC should review a proposed clinical trial within a reasonable time. [Malaysian Guideline for Good Clinical Practice §3.1.2 (GCP 4th Edition) IRB/IEC approval: Complete submission without queries can be approved within 4 to 8 weeks. Generally, MREC approval takes 50 working days. [http://www.crc.gov.my/general-clinical-trial/ Item 15] Notes: * Does not include review time by external panel of reviewers for First-In-Human Clinical Trials. ** For treatment/prevention in pandemic/endemic /public health interest. Does not include First-In-Human Trials.	The purported timeline is 60 days for the whole process.	The timing will depend on which of the three clinical trial submission routes (CTC, CTA and CTN). Clinical Trial Certificate (CTC) and Clinical Trial Authorisation (CTA): 30 working days. Note: 60 working days for cell, tissue, and gene therapy products Clinical Trial Notification (CTN): 5 working days. Clinical Research Materials Notification (CRM): Immediate Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf	For the case of standard IND application, the review timeline is 45 calendar days after submission. For the protocol with same protocol number is submitted in A10 countries simultaneously, accelerate review (Fast track system is not applicable for First in Human Study) is available and the review timeline is 15 calendar days after submission. IRB review timeline depends on each IRB review meeting frequency. The approval time may take around 1-4 months. Phase I expansion cohort is available to apply for accelerate approval process.	(Not change) Trial product import license official timeline: Chemical - 20 WD Biological - 60 WD Amendment - 20 WD IRB: (each study site or EC of MOPH) - Institute EC 2-3 months - Central EC CREC 5-6 months EC-MOPH 7-8 months.	**Registering a clinical trial**: -5 working days for ASTT to verify legality of the application -60 days for applicant to respond if needed to further complete application -5 working days after receipt of eligible application, for ASTT to grant written approval **Approving a clinical trial**: -5 working days for ASTT to verify legality of application -60 days for applicant to respond if needed to further complete application -25 days after receipt of eligible application, ASTT to meet with National Biomedical Ethics Committee and a record on clinical trial outline assessment shall be made -5 working days after receipt of record by National Biomedical Ethics Committee, ASTT submits complete application to MOH Minister for approval (if clinical trial needs correcting, applicant has 90 days)

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IND/CTA application materials	Application form If application form is needed, input "Yes" and describe country specific requirements (if any) and its language	Yes (in Chinese)	Application form for Certificate for Clinical Trial.	Yes, Application form is in English language and is called Form CT-04	Yes There is a checklist requirement Refer to BPOM regulation No.21 Year 2015 about Procedure of Clinical Trial Approval, annex I	Since September 2022, the new form, including the description of Drugs used in the Clinical Trial, has been fully implemented.	Yes IND application can be made through "nedrug web site (https://nedrug.mfds.go.kr/index)." The format of Application form should be written in Korean.	Yes Application form must be filled in English or Bahasa Melayu. (The documentation/ requirements details are provided in the Malaysian Guideline for Application of CTIL and CTX.)	Yes Form is available in the FDA website. It is in English.	Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate to HSA through PRISM.	Yes The official format of application is in Chinese. The applicant can write in by English.	Yes Local form (in Thai)	Yes, in Vietnamese or in English (Article 6, Circular 08/2022/TT-BYT)
	A statement regarding the reason why the sponsoring of the proposed clinical trial is scientifically justified	Yes (in Chinese)	Not required	Yes	Yes Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval Using Indonesian or English language	Yes (in Japanese)	Yes (in Korean)	Yes (in English or Bahasa Melayu)	Yes in English	No	Yes The official letter to indicate the sponsoring of proposed clinical trial is needed.	Yes Cover letter (have template in Thai)	No
	Protocol If protocol submission is needed, input "Yes" and describe its language	Yes (in Chinese) Protocol or draft protocol is needed	Yes, in English	Yes (in English)	Yes Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval Using Indonesian or English language	Yes (in Japanese)	Yes The protocol must be written in Korean. The protocol written in English, however, is acceptable in case of phase 1 study.	Yes (in English or Bahasa Melayu)	Yes in English	Yes, in English	Yes Either Chinese or English version is acceptable. The Chinese synopsis is requested.	Yes Guideline available, can be in Thai or English	Yes Protocol is mandatory in VNM and ENG. MOH EC members refer to ENG version to verify information.
	IB if IB is needed in the CTA/IND application, input "Yes" and describe its language	Yes (in Chinese)	Yes (in English) For Phase IV trials, HK registered pack insert can be used.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	Yes (in Japanese)	Yes. (in Korean) In case of foreign language, the original document can be required to translate in Korean (not mandatory)	Yes (in English or Bahasa Melayu)	Yes in English	Yes, in English	Yes Either Chinese or English version is acceptable.	Yes Guideline available (for unregistered drug in Thailand)	Yes In Vietnamese Or in English accompanied by a summary in Vietnamese
	CRF (sample) if CRF template (blank form) is needed in CTA/IND application, input "Yes" and describe its language	No	CRF sample is per individual IRB requirement. This is not required by Department of Health.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	If the items to be described in the CRF can be read in the protocol, it is not required.	No CRF template is not necessary for MFDS IND approval.	Yes (in English or Bahasa Melayu)	Yes in English	CRF is not included in submission dossier. It is not a requirement as per HSA guidance document.	Yes Either Chinese or English version is acceptable.	No requirement	Yes In Vietnamese or in English
	Informed Consent Form (ICF) If sample of Informed Consent Form is needed in the CTA/IND application, input "Yes" and describe its language	Yes (in Chinese)	Either in both English and Chinese, or in Chinese only.	Yes (in English) or vernacular language (as per New Drugs & Clinical Trial Rules, 2019) .	Yes, (in Indonesian or English) Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	Yes (in Japanese)	Yes. ICF template must be written in Korean. For foreign subjects, ICF templates written in foreign languages can be used.	Yes (in English or Bahasa Melayu)	Yes in English and Filipino; IC in regional/vernacular language required as applicable	Yes, in English	Yes ICF should be in Chinese and there is a template for CIRB. TFDA announced on 3-Nov-2018 that TFDA authorizes 35 IRBs for ICF amendment review and approval of drug clinical trial from 2018/11/6 to 2020/12/31.A new list of TFDA authorized IRB is released on 14 Dec, 2020. There are 36 IRBs and the period is from 01 Jan 2021 to 31 Dec. 2024. Thus, the ICF amendment is no need to submit TFDA for approval for these 36 IRBs.	Yes Local form (in Thai)	Yes, in Vietnamese and English (both are mandatory)
	Investigator's CV	No	English CV of PI.	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	No	No Information of investigational sites, investigators are required. But, CV itself is not necessary.	Yes (in English or Bahasa Melayu)	Yes in English	CV of PI, in English	Yes For both PI and Co-I, either Chinese or English version is acceptable. TFDA regulated necessary training hours needed for GCP and ethical then qualified to conduct clinical trial.	No requirement	Yes, in Vietnamese or English

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IND/CTA application materials	Overall requirement on content if "list of content" or "check list" form is needed in the application, input "Yes"	Yes (in Chinese) Adopt to ICH M4 Module1	No	Yes, as described in 5th Schedule of NDCT-19	Yes Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval Using Indonesian or English language	No	No List of content or checklist form is not required.	Yes (in English or Bahasa Melayu)	No	No	Yes The check list form for required documents is provided in Chinese.	No	No Application for approval for clinical trial consists of: a) Application form b) Documents containing information about the drug for clinical trial: - Drug trial documents: composition, manufacturing process, quality standard and drug test report (in the case of a modern drug, herbal drug or traditional drug, it is required to have a drug test report of the state-owned drug-testing facility that complies with GLP or provider of drug/medicinal ingredient testing services that complies with GLP within its scope of operation or of the manufacture that complies with GMP; in the case of a vaccine, it is required to have a quality test report of the National Institute for Control of Vaccine and Biologicals or Certification of analysis in the case of a batch of vaccines and biologicals); - Documents about pre-clinical trial of the drug that needs to be tested: reports on pharmacological effects, toxicity, safety, proposed dose, administration route and directions for use; - Documents about the clinical trial in previous phases (if the trial facility applies for permission for clinical trial in the next phases and the drug is not exempt from clinical trial in previous phases). c) Legal documents about the drug for clinical trial: - A copy of the written approval for registration of the clinical trial granted by the Administration of Science Technology and Training, the Ministry of Health. - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the application form for permission for phase 4 clinical trial submitted by the competent pharmacy authority if the drug is requested to undergo phase 4 clinical trial; - Package insert of the drug licensed for free sale if the drug is requested to undergo phase 4 clinical trial; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the trial facility's certificate of eligibility for pharmacy business; - A confirmation of participation provided by the trial centers if a multicenter trial is conducted in Vietnam; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the written approval for participation in the trial granted by the People's Committee of the province or central-affiliated city if a field trial is conducted; - A clinical trial agreement between the organization/individual that has the drug for clinical trial and the provider of clinical trial services; between the organization/individual that has the drug for clinical trial and the trial assistance organization (if any). d) A clinical trial outline and its description: - A description of the clinical trial outline - A Case Report Form (CRF); dd) Principal investigator's academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution; e) Participant information sheet and volunteer letter g) A record on scientific and ethical assessment prepared by the internal Biomedical Ethics Committee; h) Label of the drug

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IND/CTA application materials	Non-clinical summary if non-clinical reports are needed in the IND/CTA, input "Yes"	Yes (in Chinese)	No	Yes (in English)	Yes, (in Indonesian or English) Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval Using Indonesian or English language	No Non-clinical information is included in the IB.	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document. GLP data should be acquired from GLP laboratories in OECD member countries. GLP data from non-OECD member countries would be recognized if the results of the inspection from OECD member countries (include Korea) meet the GLP criteria.	Yes	Yes in English	No	No No separate document is required. Referred to IB.	No including in IB	No Not applicable (often included in IB) If provided, Vietnamese/English
	Non-clinical report	Yes (in Chinese)	No	Yes (in English)	Yes	Yes The final non-clinical safety reports are needed in the CTN of First-in-Human, if there are no clinical data on overseas. Language is in English or Japanese.	No If necessary, full report (Korean) can be requested by MFDS.	No	Yes in English	No	No No separate document is required. Referred to IB.	No including in IB	No Not applicable (often included in IB) If provided, Vietnamese/ English
	Clinical summary If clinical summary is needed, input "Yes" and describe its language	Yes (in Chinese), if there was any clinical data.	Not required	Yes (in English)	Yes	No Clinical information is included in the IB.	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document.	Yes (in English or Bahasa Melayu)	Yes in English	No	No No separate document is required. Referred to IB.	No including in IB	No NA If provided, Vietnamese/ English Clinical summary is often included in Protocol and IB.
	Clinical report	Yes (in Chinese) If there was any previous clinical date, or conduct clinical trial in other countries or the products has been marketed, the applicant should provide the whole clinical trial date, including the original and Chinese translation materials. After being approved to conduct clinical trials of drugs, the applicant shall submit regularly updated reports on safety during the period of clinical research to CDE.	Not required	Yes (in English)	Yes	No	No If necessary, full report (Korean) can be requested by MFDS.	No	Yes in English	No, HSA would require local sponsor to submit the final CSR 1 year from local LPLV, unless otherwise aligned. Sponsors also need to submit trial status report of the trial to HSA every 6 monthly, and whenever there is a change of study status (e.g. trial initiation, temporary suspension of recruitment, resumption of recruitment etc.); for IRB usually annually) Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pd	Yes Either Chinese or English version are acceptable.	No including in IB	No NA. it is often included in IB
	CMC summary	Yes (in Chinese)	Not required	Yes (in English)	Yes	No	Yes. (in Korean) In case of foreign language, the original document should be attached to the Korean document.	Yes (in English or Bahasa Melayu)	Yes in English	CMC information is included in the submission dossier, only if requested by HSA (only for CTA and CTC applications) Specifically for CTGTP, if requested by HSA, IMPD of CTGTP IND needs to fulfil the requirements stipulated in Appendix 8: Chemistry, Manufacturing and Controls Requirements for Cell, Tissue or Gene Therapy Products for Clinical Trials and Product Registration.	No However CMC data is required either in English or Chinese.	Yes See detail in guideline (for NCE)	Yes (IMPD, CoA, SmPC, label…) English/Vietnam
	CMC report	Yes (in Chinese)	Not required	Yes (in English)	Yes	No	No If necessary, full report (Korean) can be requested by MFDS.	Yes (in English or Bahasa Melayu)	Yes in English	No	Yes CMC data is required either in English or Chinese.	Yes See detail in guideline (for NCE)	Same as CMC summary

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	GMP certificate of the investigational drug	For IND of IMCT which import drug isn't marketed abroad, GMP certificate is not required, GMP statement is acceptable. For IND of China standalone study, GMP certificate is required. For CTA of 5.1 category of import drug, GMP certificate is required.	Yes	Yes	Necessary	No	Yes GMP certificate is necessary. If GMP certificate is not acquired or available, QP declaration letter should be submitted instead of GMP certificate.	Yes (Copy of Certificate of GMP Compliance for the manufacturer of drug product and/or final/batch releaser only should be submitted).	Yes in English	GMP certificate required for CTA and CTC applications. The requirements differ as per the local registration and sourcing of the product, also if its Biological and biotechnology product and Class 2 CTGTP, additional GMP certificate is required to certify that the manufacture of the drug substance is in compliance to GMP standards. Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf	GMP certificate of the investigational drug is NOT mandatory.	Yes Necessary	Yes Necessary
	Sample of the investigational drug (for IND review) if the sample of the investigational drug is needed in the IND/CTA application, input "Yes"	Not mandatory requirement, depends on if CDE has further requirements of sample testing	Sample not required, but a sample certificate of analysis of the drug is required.	Samples are requested only for Vaccine CTA applications. Samples are requested only at the time of IND application for other pharmaceutical products	No Product Information of investigational drug, CoA of investigational drug, Summary Batch protocol (Three consecutive batches) only for Vaccine, Lot release only special for vaccine.	No	No The sample of investigational product is not required.	No Sample NOT required but sample certificate of analysis of the drug is required.	No	No	No Sample NOT required.	No No requirement	No Minimal required is label mockup. Dossier still can be submitted without pictures.

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NDA	Requirement for MAH, applicant for import drugs	According to new issued Drug Administration Law, -Drug Marketing Authorization Holder (MAH) refers to enterprises or R&D institutions which hold a drug approval license. -Where the MAH is an overseas enterprise, the enterprise legal person within the territory of the People's Republic of China shall be designated to fulfill the obligations of the MAH and assume the joint liability of the MAH together.	The local subsidiary can be the MAH, while foreign company cannot be the MAH.	MAH is to be defined at the time of Import License application	Multi- National company and domestic pharmaceutical company having manufacturing license can register. Imported drug that will be registered as NDA in Indonesia is prioritized for national health program, new active substance and drug which can't be produced locally	Only the marketing authorization applicant (MAA) / holder (MAH) of pharmaceutical products may submit an NDA.	The MAH must be a locally incorporated company, corporate or legal entity in Korea. It should have importation business license from MFDS according to Article 42 of "Pharmaceutical Affairs Act"	The Product Registration Holder (PRH) must be a locally incorporated company, corporate or legal entity, with permanent address and registered with Companies Commission of Malaysia (with the scope of business related to the health/ pharmaceutical product). [DRGD §5.1]	FDA-licensed Drug Manufacturers, Traders, Distributors Any establishment that intends to import, distribute, sell, or offer for sale any imported drug product must first secure a License to Operate (LTO) as Drug Importer. (Administrative Order No. 2020-0017)	MAH holder must be a Company which is based and registered in Singapore.	Required	The local subsidiary can be the MAH and a foreign company cannot be the MAH. (Drug Act, B.E. 2510 Section 14)	The following entities may register drugs/medicinal ingredients: a) Any establishment having a license for manufacturing, wholesaling, exporting, importing drugs/medicinal ingredients in Vietnam; b) Any foreign establishment having a license for manufacturing, wholesaling, exporting, or importing drugs/medicinal ingredients in local country and having a representative office license in Vietnam.
	Acceptance of CTD format	ICH CTD format is mandatory for NDA application of both chemical drug and biological products since 1st Oct,2020	Not specified. CTD can be accepted.	Currently applications need to be submitted through online SUGAM portal and CTD sections can be uploaded as is under respective checklist as per the Sugam checklist.	ACTD (article 27 Drug Registration Guideline No. 24 year 2017) In practical, Both ICH-CTD format and ASEAN CTD (ACTD) format are acceptable by BPOM.	ICH-CTD format	According to Article 6 of "Regulation for Approval, Notification and Review for Drugs," CTD format for MA is acceptable for any drug approval. For prescription drugs which includes new drugs, and drugs that require safety & efficacy review, CTD format is mandatory	The online product registration application is based on the ASEAN CTD format. ICH format accepted with some reformatting for uploading into the online system which is structured in ACTD format (presently no change of title/numbering required)	FDA accepts NDAs following ASEAN and ICH CTD format, (Administrative Order No. 2013-0021, FDA Circular No. 2020-026)	ACTD or ICH-CTD	All new drug applications including generic application should be submitted in ICH CTD format after 1-July-2014.	Effective from 15 Feb 2023, all applications must be in eCTD or NeeS format.	ACTD and ICH-CTD format

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NDA	Category of NDA	The registration classification of chemical drugs includes ・Cat.1: Innovative drugs that are not marketed overseas and domestically; ・Cat.2: Modified new drugs that are not marketed overseas or domestically; ・Cat.3: Generic drugs applied by domestic applicant, with a drug that has been marketed overseas but not marketed domestically; ・Cat.4: Generic drugs applied by domestic applicant, with an innovative drug that has been marketed domestically. ・Cat.5: Domestic applications for drugs overseas marketed. Refer to Registration Classification and Requirements for Application Dossiers of Chemical Drugs (2020 No.44) for details. The registration classification of biological products includes ・Preventive biological products ・Cat.1: Innovative vaccines; ・Cat.2: Modified vaccines; ・Cat.3: Domestically or overseas marketed vaccines ・Therapeutic biological products ・Cat.1: Innovative biological products; ・Cat.2: Modified biological products; ・Cat.3: Domestically or overseas marketed biological products Refer to Registration Classification and Requirements for Application Dossiers of Biological products (2020 No.43) for details.	Three categories: 1. New Chemical Entity (NCE) 2. Generic (i.e. drug substance already registered at Department of Health (DOH) 3. Biosimilar	New Drug: 1) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent has not been approved as safe and efficacious by DCGI with respect to its claims; or 2) a drug approved by the CLA for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or 3) a fixed dose combination of two or more drugs, approved by CLA separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or 4) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by DCGI; or 5) a vaccine, r-DNA derived product, living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug; NOTE: The drugs, other than drugs referred to in sub-clauses (4) and (5), shall continue to be new drugs for a period of four years from the date of their permission granted by the DCGI and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs; Ref: Rule 2 (w) - New Drugs and Clinical Trial Rules, 2019 [Gazette Notification G.S.R 227(E) dated March 19, 2019]	Article 5 ,Drug registration Guideline No.24 year 2017: New Registration consist of : a. Category 1: New Drug and Biological Product registration including Biosimilar Product. b. Category 2: branded generic / generic product. c. Category 3: Registration of other dosage form with special technology, example transdermal patch, implant and beads.	For New Drugs: New Drug Application (NDA) and supplemental New Drug Application (sNDA), Generic drug application.	<Chemical> (1) New Drug 1) New chemical structure (NCE) 2) Combination drug including NCE 3) The radiopharmaceuticals that fall under 1) and 2) (2) Drugs for Safety & Efficacy Review 1) Drug with new salt, isomer or ester, etc. 2) Drug with a new indication 3) Drug with new dosage - Increase/Decrease amount of API - New combination 4) Drug with a new administration route 5) Drug with a new dosage and administration 6) Product derived from enzyme, yeast, microorganism with new origins 7) Drug with a new formulation (same route of administration) (3) Generics <Biologics> (1) New Drug 1) Vaccines 2) Antitoxins 3) Blood products 4) Blood fractionated products 5) Biologics other than above (therapeutic antigens, botulinum products, etc.) 6) Recombinant products 7) Cell culture derived products (2) Drugs for Safety & Efficacy Review 1) Biologics: strains and manufacturing methods are different from approved products 2) Product with same stock solution (API) but has different FP manufacturing sites 3) New combination of the API 4) Increase/Decrease amount of API 5) New formulation with same administration route 6) Drug with different 1st package or administration type 7) Blood product 8) (For Recombinant products and Cell culture derived products only) hosts, vectors, or different manufacturing process from approved products 9) (For Recombinant products and Cell culture derived products only) Products with different structure (except protein) from approved products 10) (For Recombinant products and Cell culture derived products only) Biosimilars 11) (For Recombinant products and Cell culture derived products only) New indication 12) (For Recombinant products and Cell culture derived products only) New combination of API 13) (For Recombinant products and Cell culture derived products only) Increase/Decrease of the amount of API 14) (For Recombinant products and Cell culture derived products only) New formulation with same administration route 15) Others (3) Changes in approval 1) New Indication 2) New dosage (same administration route) 3) New administration route 4) Changes in API amount 5) Adding Filling volume 6) Changes in manufacturing process 7-1) Changes in FP manufacturing site (add/ transfer) but with same stock solution (API) 7-2) Add or transfer of the site <Advanced biopharmaceutical drugs> (1) Cell therapy products (2) Gene therapy products (3) Tissue engineering products (4) Advanced biopharmaceutical drug (cell, gene, tissue) and medical device combination products	1) New Drug Products a. New NCE b. Hybrid NCE 2) Biologics a. Vaccines b. Blood products c. Monoclonal Antibodies d. Recombinant proteins e. Cell and gene therapy 3) Generics 4) Health Supplements 5) Natural Products 6) Veterinary Products [DRGD S.3]	(1) New drugs include: ・new chemical entities under monitored release - those not previously authorized for marketing for any pharmaceutical use in the country, including those: (1) With a new indication, (2) with a new mode of administration, (3) in a new dosage form, (4) a new fixed-dose formulation, (5) new dosage (2)Generic Prescription Drugs (3)Biologics including vaccines and biosimilars (4)Traditional Medicines (5) Herbal Drugs (6) OTC Drugs (7) Household Remedies (8) Medical Gases (9) Veterinary Drugs (10) Stem Cell Products	NDA-1 for the first strength NCE and biological entity. NDA-2 for new combination, new dosage form, new route of administration or new indication of registered chemical and biological entities. NDA-3 for subsequent strengths of a new drug product. GDA-1 for the first strength of a generic chemical product. GDA-2 for subsequent strengths of the generic chemical product.	New Drug I: (1) New chemical entity (2) New therapeutic area (3) New combination (4) New administration route New Drug 2 (1) New dosage form (2) New usage dose (3) New unit dose	1) Modern Medicine 1.1) New Drug 1.1.1) Biologics 1.1.2) Radioactive 1.1.3) New Chemical Drug NCE = New Chemical Entity, NI = New Indication, NCO = New Combination, ND = New Delivery system, NR = New Route of administration, NDOS = New Dosage form of Approved New Drug, NS = New Strength of Approved New Drug 1.2) Generic Drug 1.2.1) required bioequivalent 1.2.2) not required bioequivalent 2) Herbal Medicine 2.1) Traditional Herbal Medicine 2.2) Drug Developed from Herbal Medicine	(Law 105/2016/QH13 and Decree 54/2017 and Decree 155/2018, Circular 08/2022/TT-BYT) New registration of drug/drug material: 1. Chemical drug (new drug, generic) New drug: drugs containing new pharmaceutical substances (new chemical entities), medicinal materials, which for the first time are used for drug manufacturing in Vietnam; drugs involving a new combination of pharmaceutical substances that have been marketed or medicinal materials that have been already used in drug manufacturing in Vietnam 2. Biologicals (Biological Reference and Biosimilars) 3. Vaccines 4. Herbal medicines 5. Drug materials (API, herbal semi-product, excipients, capsule shell used for manufacturing of medicines)

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NDA	Requirement of CPP	Yes For new Cat. 1 and 2 import chemical drug and innovative therapeutic biological product (not marketed in China and overseas), CPP is not requested in the whole process of NDA. For new Cat.5.1 CPP should be submitted at the submission of CTA and NDA. Both CPP granted by manufacturing country or marketing country are acceptable. For biological products registration category still refer to No. 28 2007. For imported drugs, under COVID-19 pandemic, if the original certification documents which have been notarized and legalized abroad cannot be mailed, or the documents cannot be notarized or legalized, the overseas license holder or the registration agent shall explain in the "special declaration matters" in the application form and submit the electronic scanned version of the certification documents, Need to submit all the corresponding original notarized and legalized documents at a time before approval. In addition, electronic certification documents issued by overseas drug regulatory agencies are acceptable. In view of the FDA policy adjustment on CPP issuance, it is agreed that for FDA-approved products exported to the USA from countries outside of the USA, the CPP can no longer be provided when registration applications are submitted in China and the applicant can provide the screenshot of the FDA website or other certified documents etc. to support filing of the registration application.	To be submitted at the time of application No. of CPP required: NCE: 2 ICH countries (including source country) or 1 ICH & 1 ICH but non-SRA countries, including China, Brazil, Singapore and South Korea (including source country) Generic: 1 (source country only) Biosimilar: 1 country approval (source country) from the 5 referenced countries	CPP or Free sale certificate (FSC) issued by country of origin is required at NDA. The CPP and FSC should be notarized and apostilled or legalized.	Yes Copy of CPP for pre-registration and registration is accepted since currently NDA registration is performed by online electronic registration. Annex , Drug Registration Guideline No. 15 year 2019 One CPP could be utilized as supporting docs for Path 120 WD (reliance) and 300 WD. For Path 120 WD (reliance), BPOM refer to reference countries: EU, US, Australia, Canada, England & Japan. Applicant can choose 1 country as reference. Several requirements are necessary, e.g. unredacted assessment report from reference countries, same quality document with reference country, etc.	No	CPP is not mandatory. - Imported drugs that are manufactured at sites that were not assessed as qualified for the KGMP by the MFDS, certificate of manufacture that describes the name and location of manufacturer, etc. and which those that prove they are appropriately manufactured in the country of manufacturing of the relevant items.	Yes The CPP with a marketing status should be submitted at the time of registration application. Currently, exception to submit CPP during the review may be considered based on unmet medical need justification. CPP is only required for imported product. CPP from the competent authority in the country of origin (or GMP Certification/ Manufacturing License for the manufacturer from the relevant competent authority, together with CPP from the country of the product owner; or CPP from country of release, if CPP from the country of origin is not available.) CPP shall be in the format of WHO Certification Scheme on Quality of Pharmaceutical Products Moving in International Commerce. Unless otherwise supported by justifications acceptable to the Authority, the following products are unlikely to be registered: i) products not licensed/ certified for sale in the country of manufacture/ product owner; ii) products manufactured for export only (imported products). [DRGD Appendix 29] .	Yes One CPP is required to be submitted from the source or any reference country. Must indicate that it is registered and freely sold in that country	No Submission of CPP is not compulsory as a form of proof of approval. The proof of approval must come in the form of an official approval letter or equivalent document (e.g. CPP) issued by the National Medicine Regulatory Authority which certifies the registration status of the product (not provincial/ territory/ or state agencies). CPPs that indicate that the product is not licensed in the exporting country (including the scenario where the product is licensed "solely for export only") are not acceptable proof of approval.	Yes CPP(s) are required before drug license collection. The detail is as the same as 2022. Amendments of "Regulations for Registration of Medicinal Products" for A10 CPP legalization exemption in 2020.	CPP is required at the timing of approval. 1 CPP from any country with marketed status. The product detail has to be supplemented to the CPP: ·Required Trade name ·Must include sales statement ·Manufacturing sites at least DP manufacturer and primary packager ·Product formula at least active ingredient and in percentage display	**<u>Requirements for a CPP</u>** (Art. 22, Circular 08/2022/TT-BYT) 4. Requirements for a CPP: a) A CPP must be issued by the competent authority and cover all the information required in the WHO-model CPP published on WHO's web page (https://www.who.int/) b) A CPP must bear the signature, name of the signer, issue date and the seal of the CPP issuing authority; If the CPP does not bear the certifying seal of issuing country's competent authority, the registrant shall provide supporting documents proving that as a rule in the issuing country a seal is not required on CPP. d) With regard to **imported new pharmaceuticals, vaccines, biologics, other than probiotics:** A CPP issued by the manufacturing country's competent authority certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. If the CPP-issuing competent authority of the manufacturing country is among the authorities on the list stipulated in clause 9 Article 2 of this Circular, submission of just 01 CPP shall suffice. If the CPP-issuing competent authority of the manufacturing country is not on the list stipulated in clause 9 Article 2 of this Circular, additional official papers issued by a regulatory authority of the countries on the list stipulated in clause 9 Article 2 of this Circular certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. The official paper should cover at a minimum the following information: drug name, drug substance, strength or concentration of drug substance, dosage form, name and address of manufacturer or supporting documents proving that that the drug is of the WHO list of prequalified medicines. đ) With regard to drugs that are the subject of application for **brand name drug, or reference biologic designation:** A (01) CPP issued by the manufacturing country's competent authority certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. If the CPP-issuing competent authority of the manufacturing country is among the authorities on the list stipulated in clause 9 Article 2 of this Circular, submission of just 01 CPP shall suffice. If the CPP-issuing competent authority of the manufacturing country is not on the list stipulated in clause 9 Article 2 of this Circular, additional official papers issued by a regulatory authority of the countries on the list stipulated in clause 9 Article 2 of this Circular certifying that the drug product is licensed for marketing and is actually marketed in the relevant country shall be required. The official paper should cover at a minimum the following information: drug name, drug substance, strength or concentration of drug substance, dosage form, name and address of manufacturer. e) With regard to **imported drugs, vaccines, biologics for which a CPP meeting the requirements of point c, d of this clause cannot be provided**, the Minister of Health shall review the case based on the advices from the Council providing that such a drug product has been licensed for marketing by at least one regulatory authority in the world and falls into one of the categories: - Drugs, vaccines, biologics to meet emergency requirements in national defense, national security; for the prevention, combatting of epidemics, diseases, for the mitigation of consequences of natural disasters, calamities drugs for the service of health programs of the states; - Vaccines for the use in national expanded immunization programs, for which there are no substitutable vaccines readily available in the market in terms of quantity, quality, safety, efficacy or cost of use; - Other specific cases covered by agreements, mutual recognition between competent authorities regarding the conditions for manufacturing and marketing of drugs, vaccines, biologics. g) Information recorded on a CPP must be consistent with relevant information in the registration dossier of the drug. Where information recorded on a CPP is not consistent with the administrative documents of the registration dossier, the registrant shall submit an explanatory letter along with supporting documents. **<u>Reference regulatory authority</u>** (Art. 2 Circular 08/2022/TT-BYT) 9. European Medicines Agency (EMA) and the Stringent regulatory authorities (SRA) are: a) The European Medicines Agency (EMA); b) The Stringent regulatory authorities (SRA) are authorities categorized by the World Health Organization (WHO) as belonging to the SRA list, which are: - Members of the ICH before 23 October 2015, comprising: US Food and Drug Administration (FDA), the pharmaceutical regulatory authorities European Union countries, the UK Medicines and Healthcare products Regulatory Agency (MHRA) Japan Pharmaceuticals and Medical Devices Agency ((PMDA) - Observer members of ICH before 23 Oct 2015, comprising pharmaceutical regulatory authorities of European Free Trade Association (EFTA) and Swiss regulatory authority (Swiss medic), and Canada Health Ministry (Health Canada). - Regulatory authorities associated with an ICH member through a legally-binding, mutual recognition agreement before 23 Oct 2015, including Australia, Iceland, Liechtenstein, and Norway.

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NDA	Acceptance of foreign clinical trial data. (Can approval be obtained by utilizing foreign clinical trial data?)	Yes -For innovative drugs, clinical trial data obtained overseas of simultaneous development in China and overseas is acceptable. -For generic drugs, integrated BE study data obtained overseas can be used for registration application in China. Data should incudes bioavailability/BE study, PK/PD study, safety and efficiency data in accordance with ICH E5, should meet ICH GCP and China registration requirement. Acceptance includes, 1) Completely acceptable 2) Partial acceptable: Supplemental trial required after communication with CDE. -For serious diseases, rare diseases and pediatric diseases lacking of effective treatment, if the data can be partially accepted after evaluation, post-marketing study for efficiency and safety is required. 3) Not acceptable.	The overseas clinical trial data is acceptable. Bridging data are not required.	Local clinical trial is required however exemptions can be explored on case to case basis in case of following conditions: • New Drug is approved/marketed in countries (as specified by DCGI) & no major unexpected serious adverse events associated with the product – the countries have not been specified as yet. • Where India has been included in clinical development of the product (phase2/3 global studies), or is part of ongoing studies – inclusion of India in phase 2/3 clinical development is an advantage for faster marketing approval • There is no probability or evidence of difference in Indian population wrt ADME, PK-PD, safety and efficacy of the new drug • Applicant provides undertaking to conduct Phase IV clinical trial – most waivers in the past year have been granted with this condition • The above conditions may be relaxed if the drug is indicated for: — life threatening or serious diseases or — diseases of special relevance to Indian health scenario or — for a condition which is unmet need in India (XDR TB, Hep C, H1N1, Dengue, Malaria, HIV, rare diseases) Orphan drug	Yes Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guideline. Local regulatory trials are required for TB program and drug for family planning program	Yes The data from overseas clinical trial is accepted in accordance with ICH E5. The drugs approved using global clinical trial data have increased. However, the Japanese PK data is indispensable.	Yes For new drugs, bridging data is needed For generics, bioequivalence data from Koreans is generally used. In the case of OTC drugs, in principle, bridging data is exempted.	Yes Overseas clinical trial data is acceptable, as long as it is aligned with ICH and/or WHO guidance, and accepted by the major reference countries. Local clinical trial data in diseases of public health interest may be considered to support priority review. • New Chemical Entity (NCE) or biologics product with phase III pivotal clinical trial conducted locally in Malaysia for the treatment of diseases of public health significance (e.g., hepatitis, HIV, COVID-19, etc.). A minimum of 10% of the total number of randomized subjects are subjects in the clinical studies conducted at study sites in Malaysia [DRGD Appendix 12]	Yes There is no requirement for local clinical trial data (Phases I-III) for registration.	Yes Overseas clinical trial data is acceptable.	Yes, foreign clinical trial data is acceptable. However, BSE is mandatory for NDA and BLA. Drugs received Designation Request of Medications for Pediatric Population or the Minority Patients with Serious Diseases from the central health authority, cellular and gene therapy products are exempted from the BSE according to the amendment of the “Regulations for Registration of Medicinal Products” announced on 14th Sep 2021.	Yes	Yes The clinical trials on drugs, the clinical data included in clinical documents must be in line with guidelines of ICH, Vietnam Ministry of Health or other organizations recognized by Vietnam (international organizations to which Vietnam is a member, regulatory authorities specified in Clause 9 Article 2 of this Circular), except for the case specified in Clause 3 of this Article. If clinical trials are conducted before the above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Art. 13, Circular 08/2022/TT-BYT

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NDA	Application fees	New standard for drug registration fee was published by NMPA, refer to https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200630211101986.html for details.	Application fee: HKD 1100 License fee: HKD 1370 Renewal fee (every 5 years): HKD 575	As per Sixth Schedule of New Drugs and Clinical Trial Rules, 2019 (FEE PAYABLE FOR LICENCE, PERMISSION AND REGISTRATION CERTIFICATE)	Annex, President Regulation No. 32 year 2017 on type & tariff for drug registration: Application fee: Pre-Registration: 1 Million IDR (MIDR) Registration fee for: Category 1: new product & Biological Product: 30 MIDR, new indication: 20 MIDR Category 2: Branded generic product 7.5 MIDR, copy product with BA/BE data: 12.5 MIDR, generic product 1 IDR Category 3: other product: 7.5 MIDR On site Inspection IDR 50 Mio (excluding transportation & accommodation of inspector)	The application fee was revised on Sep 1, 2020. Application fees for drugs containing new active ingredients (in case of non-orphan drug) are: To Government: 533,800 yen To PMDA: for review: 36,538,400 yen for paper-based compliance inspection: 10,363,300 yen for GCP inspection: domestic 4,302,300 yen, and overseas 4,758,500 yen +travel expenses for GMP inspection: domestic 1,008,700 yen, and overseas 1,272,900 yen + travel expenses	Application fee are defined in the Annex 1 of the "Regulation of Fees for Approval of Medical Products"	Fees are required and details are given in the DRGD Appendix 9: Fees. These are according to product categories, number of active ingredients, types of applications etc. Currently, fee increments are under review.	New drug application for NCEs is PhP40,000.00 plus Php 500.00 for brand name clearance New drug application for other categories depend on existence of brand names: •Branded: PhP15,000.00 plus Php 500.00 for brand name clearance •Unbranded: PhP10,000.00	<u>For therapeutic product</u> Registering a product – NDA & GDA a) Screening (Payable upon submission) (i) Abridged/Verification evaluation route (NDA & GDA) $580 (ii) Full evaluation route (NDA) $2,910 b) Evaluation (Payable upon acceptance) (i) NDA Abridged evaluation route - NDA-1 & NDA-2 $11,400 - NDA-3 $5,830 (ii) NDA Verification evaluation route - NDA-1 & NDA-2 $16,900 - NDA-3 $5,830 (iii) NDA-1,2,and 3: Full evaluation route $82,900 (iv) GDA Abridged evaluation route - GDA-1 $4.080 - GDA-2 $2,330 (v) GDA Verification evaluation route - GDA-1 $10,400 - GDA-2 $5,300 (vi) GDA Verification evaluation route (CECA Scheme) - GDA-1 $10,400 - GDA-2 $5,300 C) Annual retention fee (per registered product) - NDA & GDA $318 HSA website: https://www.hsa.gov.sg/therapeutic-products/fees <u>For Class 2 CTGTP</u> Full route application for NDA-1/2/3: - Screening: $2,900 - Evaluation fees: #82,700 Abridged route application: - Screening: $570 - Evaluation fees for NDA-1/2: $13,700 - Evaluation fees for NDA-3: $5,700 Annual retention fees per registered product: $310 HSA website: https://www.hsa.gov.sg/ctgtp/fees-and-turnaround-time	"Standards of Review Fees for the Registration of Western Medicines" was amended in 2020 and became effective in 2021. "Standards of Review Fees for the Registration of orphan drug" was amended and became effective on 1-Jan 2022.	Effective 4 Aug 2017, new fee is applied to all types of applications except A) a new drug that is researched, developed and manufactured locally for national security as notification of the Minister of Public Health B) an orphan drug that has items in accordance with the Notification of the Food and Drug Administration C) a drug registered and needs revision as the Ministry of Public Health, or the Food and Drug Administration stipulates regarding quality and safety problems	NDA: 250 USD (5.500.000 VND) Renewal (So-called extension): 135 USD (3.000.000 VND) Variation: 50 USD (1.000.000 VND)

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	Other requirements	Simultaneous development and registration of vaccine is opened Optimize registration process: Change sequential process to parallel, e.g., pre-NDA QC testing and GCP Inspection Since Jul.1st, 2021 for imported drugs, the repackaging process has been updated to 1)NDA submission and approved by NMPA/CDE, receive drug approval license, 2)CDE filing for large package→3)CDE filing for repackage Removed MTP requirement from CTA dossier Additionally, NMPA issued Announcement on Implementing Electronic Application of Drug Registration (2022, No. 110) on Nov.30, 2022, indicated that since Jan.1 2023, as of Jan 1, 2023, the drug registration applications reviewed and approved by NMPA and the supplementary dossiers during the review shall be adjusted to be submitted in electronic form, and the applicants no longer need to submit paper application dossiers. Existing working procedures remain unchanged. Upon the implementation of this Announcement, if the applicant makes drug application by eCTDs, paper application dossiers are no longer needed, and other requirements shall still be implemented in accordance with the Announcement on Implementing the Application with Electronic Common Technical Documents for Drugs (No. 119 [2021]).	-	Import License is required after marketing approval and Registration Certificate. India has a mandatory testing requirement at the time of import of first commercial shipment. After first shipment, testing is conducted as per following schedule- 1. Vaccines- Every Imported Batch 2. Plasma Derived Products- Every Imported Batch 3. Biologicals- Once every 6 months Small Molecules- At port officers discretion	Specific country requirement on product labeling on product package, example: font type and size of the generic name, retail price, symbol of prescription drug, the name of importer. Site Master File, Established Inspection Report within 2 years, GMP certificate and Manufacturing License are requested for non registered overseas factories at submission. Inspection may be conducted against overseas factories if necessary	-	-	Other requirements are as noted in the DRGD.	•Reference Standard Sample (at least 300 mg; subject to FDA advise when to submit) •Compliance to foreign GMP requirements (before submitting NDA, applicants must first secure a Certificate of GMP Compliance from FDA for each foreign manufacturing site involved in the final product [Administrative Order No. 2013-0022 and FDA Circular No. 2014-016]) •Local generic labeling requirements (Administrative Order No. 2016-0008) •Registration sample/s mocked-up in the proposed commercial and sample labeling presentations, including the corresponding Certificate of Analysis (subject to FDA advise when to submit)	For GDA, the reference product must be the registered product with Singapore HSA Batch numbering system is required for registration of generics and branded innovators Singapore-Specific Annex may be required for submission of risk management plan in support of NDA, GDA and MAV applications.	-	In case of biological products, local lab test by DMSC will be required in parallel with registration.	Site master file*, Labeling, Package Insert, COA for Drug Substance and Drug Product, Trademark, AF, LoA, legal documents of applicant, RMP (vaccine)And for vaccines, antiserum, blood extracts and human plasma below document is requested: a) The batch release certificate issued by a competent authority of the country in which the CPP is issued; b) The test report, specifications and test method certified by VN National Institute for Control of Vaccines and Biologicals (NICVB); Registration certificate for trademark in Vietnam is required if there is ® symbol on labeling *: Decree 54/2017/ND-CP requires Evaluation on following good manufacturing practice (GMP) of MFR. Legal documents proving compliance with GMP submitted by a manufacturer of active ingredients, excipients, capsule shells, semi-finished herbal ingredients and herbal ingredients (for manufacture of herbal drugs) may be any of the following documents: a) The GMP certificate; b) The manufacture license that certifies GMP compliance; c) The CPP if the active ingredient is conformable with GMP; d) The Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP). đ) With regard to excipients in registration dossiers for finished drug products, drug raw materials being semi-finished products: If manufacturer cannot provide certificate of a, b, c, the manufacturer can provide Self-declaration as Form 13/TT GMP Principles and Standards for production of pharmaceuticals have been applied by administration of country or other international organization. (Circular 32/2018/TT-BYT, 29/2020/TT-BYT)

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NDA application materials	CMC summary	Yes (in Chinese)	Yes For NCE/Biosimilar only (document in English).	Yes, in English	Yes (in Indonesian or English as in part II Quality) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VII	Yes Only Japanese as M2.3 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English.	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part II in English	Yes (in English)	Yes (In English as M2.3 in CTD)	Yes	Yes QOS of DS, DP Vietnamese or English
	CMC report/body of data	Yes (in Chinese)	Yes For NCE/Biosimilar only (document in English).	Yes (English is acceptable as M3 in CTD)	Yes (in Indonesian or English as in part II Quality) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VII	Yes English is acceptable as M3 in CTD	Yes M3 in CTD: English is acceptable.	Yes (Part 2 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part II in English	Yes (in English)	Yes (In English as M3 in CTD)	Yes In addition to ACTD on Quality Part II (or ICH CTD Module 2.3), the Certificate of Analysis for Finished product (3 batches), API (for at least 2 batches from API manufacturer and DP manufacturer), Excipient (at least 1 batch).	Yes Vietnamese or English Quality dossier shall be prepared in conformance with the guidelines of ACTD - Part II or Module 3-ICH-CTD. - Drug substance (S): General Information (S1); Manufacture (S2); Characterization (S3) and Control of Drug Substance (S4), Reference Standards or Materials (S5); Container Closure System (S6) and Stability (S7); - Drug product (P): Description and Composition (P1); Pharmaceutical Development (P2); Manufacture (P3); Control of Excipients (P4); Control of Finished Product (P5); Container Closure System (P7). Reference Standards or Materials (P6); Stability (P8) and Product Interchangeability Equivalence evidence (P9) if applicable
	Non-clinical summary	Yes (in Chinese)	Yes For NCE/Biosimilar only (document in English).	Yes, in English	Yes (in Indonesian or English as in part III Non Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VIII	Yes Only Japanese as M2.4, M2.6 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English.	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part III in English	Yes Only for full dossier, in English	Yes (In English as M2 in CTD)	Yes ACTD on Non-Clinic Part III or ICH CTD Module 2	Yes Vietnamese or English The non-clinical document shall be prepared in conformance with the guidelines of ACTD - Part III or Module 4-ICH-CTD.

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	Non-clinical report	Yes (in Chinese)	Yes For NCE/Biosimilar only (document in English).	Yes, (English is acceptable as M4 in CTD)	Yes (in Indonesian or English as in part III Non Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex VIII	Yes English is acceptable as M4 in CTD	Yes M4 in CTD: English is acceptable	Yes (Part 3 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part III in English	Yes Only for full dossier, in English	Yes (In English as M4 in CTD)	Yes ACTD on Non-Clinic Part III or ICH CTD Module 4	Yes for new chemical drugs, vaccines, and biologicals The no-clinical trials shall be prepared in conformance with the guidelines of ACTD - Part III or Module 4-ICH-CTD. Vietnamese or English, and in both soft-copy (into a USB) and hard-copy Letter 72/QLD-DK/2018 and ACTD guidelines on Non-Clinical data mention that Non-clinical summary is enough. Non-clinical report is only required when VN authority wants to double check the summary. In that case, the content of Non-clinical report includes: 1. Pharmacology 1.1 Primary Pharmacodynamics 1.2 Secondary Pharmacodynamics 1.3 Safety Pharmacology 1.4 Pharmacodynamics Drug Interactions 2. Pharmacokinetic 2.1 Analytical Methods and Validation Reports 2.2 Absorption 2.3 Distribution 2.4 Metabolism 2.5 Excretion 2.6 Pharmacokinetic Drug Interactions 2.7 Other Pharmacokinetic Studies 3. Toxicology 3.1 Single dose toxicity 3.2 Repeat dose toxicity 3.3 Genotoxicity 3.4 Carcinogenicity 3.5 Reproductive and Development Toxicity 3.6 Local Tolerance 3.7 Other Toxicity Studies
	Clinical summary	Yes (in Chinese)	Yes For NCE/Biosimilar only (document in English).	Yes, in English	Yes (in Indonesian or English as in part IV Clinical Data) Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex IX	Yes Only Japanese as M2.5, M2.7 in CTD	Yes M2 in CTD in principle should be Korean, but Tables, etc. may be written in English	Yes (Part 4 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part IV in English	Yes (in English)	Yes. (In English as M2 in CTD)	Yes ACTD on Clinic Part IV or ICH CTD Module 2	Yes for new chemical drugs, vaccines, and biologicals The clinical trials shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD. The clinical document shall be prepared in conformance with Letter 72/QLD-DK/2018 by both hard-copy and soft-copy.
	Clinical report	Yes (in Chinese) According to newly issued, it is no necessary to provide site summary report (SSR) for the submission in Clinical Study Report (CSR)	Yes For NCE/Biosimilar only (document in English).	Yes, (English is acceptable as M5 in CTD)	Yes (in Indonesian or English as in part IV Clinical Data). Indonesia required full clinical study report Refer to regulation BPOM No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration, annex IX	Yes English is acceptable as M5 in CTD	Yes M5 in CTD: English is acceptable	Yes (Part 4 in ACTD) - in English or Bahasa Malaysia	Yes ACTD Part IV in English	Yes (in English)	Yes. (In English as M5 in CTD	Yes ACTD on Clinic Part IV or ICH CTD Module 5	Yes for new chemical drugs, vaccines, and biologicals The no-clinical trials shall be prepared in conformance with the guidelines of ACTD - Part IV or Module 5-ICH-CTD. Vietnamese or English Letter 72/QLD-DK/2018 and ACTD guidelines on Clinical data mention that for hard copy list of clinical trails is enough. Clinical report is only required when VN authority wants to double check the summary. In that case, the content of Clinical report includes: 1 Reports of Biopharmaceutic Studies 2 Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials 3 Reports of Human Pharmacokinetic (PK) Studies 4 Reports of Human Pharmacodynamics (PD) Studies 5 Reports of Clinical Efficacy and Safety Studies 6 Reports of Post-marketing Experience 7 Case Reports Forms and Individual Patient Listing

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NDA application materials	Other required documents	CDE Announcement on effected since July.1st According to NMPA Announcement on Implementation of Drug Common Technical Document Electronic Submission (No. 119, 2021) issued by NMPA on Sep.30, 2021, since Dec. 29, 2021, for Cat.1 and Cat 5.1 of chemical drugs, Cat. 1 of therapeutic biologicals and Cat.1 of preventive biologicals, follow eCTD for the NDA submission. The Applicant should follow eCTD technical documents to prepare and submit eCTD submission dossier CD, and submit paper materials within 5 WDs after acceptance. eCTD Technical Specification V1.0, eCTD Verification Standard V1.0 and eCTD Implementation Guideline V1.0 were issued as well.	All documents in English. General requirements: 1.An authorization letter from the overseas manufacturer for the applicant; 2.Soft copy of the business registration certificate; 3.Soft copy and certified true copy of the manufacturer's license; 4.Methods, standards and conditions of the manufacture of the pharmaceutical product, manufacturing and quality control facilities, technical personnel, etc.; 5.Soft copy and certified true copy of GMP certificate which meets PIC/S GMP standards; 6.Soft copy and original or certified true copy of CPP from the country of origin; 7.One set of prototype sales pack for each pack size, complying with the labelling requirements; For NCE or biological entity: 8.Soft copy and original or certified true copies of CPP from 2 or more of the "acceptable" countries; 9. Expert evaluation reports on the safety, efficacy and quality of the product. CV of the expert and the expert's signature on the corresponding reports are required; 10. EU-RMP and or FDA REMS. Information on whether any of the risk management plan activities and mitigation strategies will be implemented in HK; 11. Proposed package insert of the product. Where the package insert is in the form of a patient information leaflet, a prescribing information leaflet for healthcare professionals for use in HK should also be submitted. The following document(s) to support the proposed indication(s), dosage, route of administration and other contents of the package insert (if any); 12.A copy of reputable reference; 13.Documentary evidence showing that the package insert has been approved by one of the listed countries; 14. Master formula (Batch formula not accepted) - Non-proprietary names of ingredients, colour Index number or E-number for all colourants used should be provided; 15. Finished product specifications; 16. Method of analysis 17. COA of a representative batch 18. Stability data 19. Bioequivalence data for anti-epileptic drugs and critical dose drugs The BE studies should be conducted in accordance with World Health Organization guidance on the "Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability" or other international guideline. 20. Safety documents for ingredients with animal origins About Biosimilar guideline, please refer "Guidance Notes for Registration of Biosimilar Products" (Aug 2021)	As described in Chapter X (IMPORT OR MANUFACTURE OF NEW DRUG FOR SALE OR FOR DISTRIBUTION) of New Drugs and Clinical Trial Rules, 2019 The Module 1 of NDA in Sugam expects submission of multiple legalized documents including Power of Attorney, CPP, GMP certificate etc.	See BPOM Regulation No.24 Year 2017 regarding the Criteria and Procedure of Drug Registration See BPOM Regulation No. 15 Year 2019 on amendment to regulation of BPOM Regulation No.24 Year 2017.	CTD M1 and M2 are acceptable only in Japanese. CTD M1: 1.1 Table of Contents 1.2 Approval application (copy) 1.3 Various certificates 1.4 Patent information 1.5 Data concerning the origin or background of development 1.6 Information on the use of the drug in foreign countries 1.7 List of similar products from the same therapeutic category with similar efficacy 1.8 Package insert 1.9 Documents pertaining to the non-proprietary name of the drug 1.10 Summary of data pertaining to the designation as a toxic drug, etc. 1.11 Master plan for post-marketing surveillance 1.12 List of attached data 1.13 Other data	Module 1 1.1 Table of contents of Module 1 1.2 Application form or approval application (Copy) 1.3 Statement and Signature of the person in charge of preparation of CTD, His/Her information(career) 1.4 Statement and Signature of the translator 1.5 Status of the product usage in foreign countries 1.6 Information on properties of the product including comparison with similar products that were approved in Korea. 1.7 Various documents related to Regulations on Safety of Pharmaceuticals Article 4 (1) 1.7.1 Bioequivalence test data/ Dissolution test data 1.7.2 CPP 1.7.3 GMP data 1.7.4 DMF data 1.8 Contract documents (In case any process during manufacturing, QC test is outsourced) 1.9 LTOC 1.10 Package insert(draft) 1.11 Other data	In English or Bahasa Malaysia: ACTD Part I: Administrative Data & Product Information Section A: Product Particulars Section B: Product Formula Section C: Particulars Of Packing Section D: Label (Mockup) For Immediate Container, Outer Carton And Proposed Package Insert Other admin doc: CPP, LOA, CA, GMP CE	A RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Module 1 (or ACTD Part Ⅰ) documents e.g., Letter of authorizations Declaration on rejection, withdrawal and deferral Artwork of packaging material GMP certificate Patent declaration Reference country/product approval and approved package insert, if applicable Registration status in other countries Confirmation of Reference Agency's Approval of Chemistry & Manufacturing Control (CMC) Aspects required for both GDAs and innovator brand's NDAs, if submitted under abridged route and for which approval in at least one of HSA's reference agencies not more than 5 years before the date of submission to HSA, plus completed Dossier Clarification Supplement.	NDA RTF checklist was revised on 2-Nov-2021 announced by TFDA.	E-Submission for all applications.	Other requirements For filing dossiers: Letter 72/QLD-DK/2018 regulate as follows: -Each part should be filed certainly in one or some files and arranged according to the following order: + Part I, Part II + Part III, Part IV + BE/BA report + Evaluation on following GMP of MFR. - BA/BE report: should include 1 extra package insert. - Part III, Part IV: should be submitted with 1 copy of the package insert, SmPC, and both soft copy (in USB) and hard copy with the same content. - Each section of the hard copy dossier must be certified by the applicant or the manufacturer of the drugs on the first page (the representative office's seal is also acceptable). -Data in soft copy should be written as searchable PDF. - Dossier code, dossier type, product name, and applicant name should be written on the package of USB; - For online submission: b) The implementation roadmap for online submission shall be in accordance with the Ministry of Health's stipulation. From the date online submission is fully applicable, registrants shall submit registration dossiers electronically online in accordance with point a of this clause. Where there is a need for paper-based dossier for review, cross-referencing, Drug Administration shall issue a request to the effect. (Art. 6(b), Circular 08) - Official Letter 9459 / QLD-DK dated June 30, 2020, regulates that applications for NDA and renewal of MA shall be uploaded to the online public system of HA before submitting them in hard copy. - Legal documents in the dossier must be valid at the time of receiving the dossier. -The number of MAs for drugs with the same active ingredient; dosage forms; route of use; content or concentration: 01 drug by trade name and 01 drugs by international generic name. - A registrant establishment is only allowed to amend and supplement no more than 03 times for the application for issuance, renewal (so-called) extension, or variation of the marketing authorisation of drugs and medicinal ingredients (Art. 35, Circular 08/2022)

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NDA Approval review	Review organization (names of "review organization", "decision organization", "advice committee" etc)	Review: CDE (Center for Drug Evaluation) Decision: NMPA (Notional Medical Products Administration) Inspection: CFDI of NMPA (Center for Food and Drug Inspection) Registration Testing: NIFDC (National Institutes for Food and Drug Control)	Review: Drug Office, DOH Approval: Pharmacy and Poisons Board	Technical review is conducted by CDSCO and Subject Matter Experts (SME) are invited by CDSCO for joint review of clinical and non-clinical data. Final decision is taken by CDSCO based on recommendations from Subject Expert Committees	BPOM regulation No. 15 year 2019 on Amendment to regulation of Head BPOM No. 24 year 2017 article 45 and article 49 1. Committee of Safety-Efficacy Evaluation with the task of evaluating the safety and efficacy aspect to be discussed in the periodic meeting of National Committee/ KOMNAS. 2. Committee of Quality Evaluation with the task of evaluating the quality aspect. 3. Committee of Product Information Labeling Evaluation with the task of evaluating in the aspects of Product Information and Labeling."	Review PMDA (Pharmaceutical and Medical Device Agency) Decision MHLW (Ministry of Health, Labor and Welfare) Advice CDFS (Council on Drug and Food Sanitation)	[Review] ・ NIFDS ・ Regional Office of MFDS [GMP inspection] ・ MFDS Headquarter (for imported products, foreign manufacturing sites) ・ Regional Office of MFDS (domestic, for manufacturing sites located in Korea) [Decision] ・ MFDS Headquarter ・ Regional Office of MFDS (Products of Notification, Generics) [Advise] ・ Central Pharmaceutical Affairs Council	Review: National Pharmaceutical Regulatory Agency (NPRA) Advice: NPRA's Review Committee Decision: DCA (Drug Control Authority)	Review and Decision The Center for Drug Regulation and Research (CDRR) of the FDA Advice The FDA may hire external consultants for data requiring specific expertise (e.g. clinical and non-clinical data, abortifacient properties, etc)	HSA (Panel of internal and external reviewers.)	Review center is composed of TFDA and CDE. Drug Advisory Committee provides consultation during the review and further endorses the CDE review if there are special issues. Decision organization is TFDA.	Review Thai FDA, External Reviewer Decision Thai FDA Advice Drug Committee	Drug Administration of Vietnam (under the Ministry of Health); expert from Institutions, university in Hanoi, Ho Chi Minh city. The DAV assigned 3 universities (so far) as affiliated dossier review centres. Decision organization, Advice committee: Drug Committee with members include Ministry of Health, KOLs from Universities and Institutions.
	Number of reviewers	Around 700 in CDE, no exact numbers in sub centers of the Yangtze River Delta and the Greater Bay Area. Real-time recruitment information could be referred to from CDE website (https://www.cde.org.cn/gkzp/index)	Undisclosed	Over 20 Subject Expert Committees constituted by CDSCO with a pool of >500 Experts from all the therapeutic areas. The composition of SECs is flawed and their decision-making process is non-transparent and fairly arbitrary and unpredictable.	No information on amount of reviewer in regulation for each section committee.	All staff: 978 Review Dept.: 582 Safety Dept.: 181 (As of Feb.1,2022)	There is no official information	The Product & Cosmetic Evaluation Centre in NPRA has 130 officers currently. Other regulatory support are provided by the Regulatory Coordination & Strategic Planning Centre, and the Compliance & Quality Control Centre.	CDRR has 51 reviewers	unknown	CDE is responsible for drug registration review and consultation service, there are 304 staffs including non-reviewers. Among these manpower, 104 staffs are responsible for drug & medical device review, including Clinical, Non-clinical, CMC, PK/PD, Phar,/Tox and statistical until 31-Dec-2021.	-	5 Sub-committees (Groups), with 2-3 experts/reviewers in each Group (Legal; Quality & Specification; Pharmaceutical & stability; Pharmacology; Clinical)

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NDA Approval review	Review process/flow	Refer to for the enclosed review process of CDE Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Implementation) was issued by CDE on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Working Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) were issued by CFDI on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Additionally, CDE issued Working Procedures for Changes During the Review of Drug Registration Application (Trial) on Nov.11, 2022, including 1)Changes during the review of drug clinical trial application and supplementary application during clinical trials, 2) Changes during the review of drug marketing authorization application, 3) Changes during the review of post-marketing supplementary application and re-registration application for drugs manufactured overseas. CDE issued Management Practice for Suspension and Resumption of the Review Timing in the Evaluation Process of National Medical Products Administration (Trial) (Yaoshenye [2022] No.614) on Nov.16, 2022, applicable to the registration application of all types of drugs (including APIs) and the related application of pharmaceutical excipients and drug packaging materials, including the drug marketing authorization application, drug supplemental application, renew application of imported drugs, consistency evaluation application, etc.	Undisclosed	New Drug approval is a three steps process for imported products namely- NDA, Registration Certificate, and Import License. Parallel submission and review are acceptable for NDA and Registration Certificate	Pre-registration review document until complete documents --> Payment of pre-registration fees-->submit pre-registration --> Evaluation--> Approval Pre-Registration Registration review document --> Payment of registration fees --> Submit registration documents --> Clock start of registration review /Evaluation Approved Registration Number Currently all registration processes are performed in e-reg (New Aero system). Master data registration is necessary to be completed for API, all excipients, API manufacturer, excipients manufacturer & drug product manufacturer prior apply in electronic registration system. According to BPOM regulation No. 15 Year 2019, Approvable letter was removed. Approvable letter would be issued only for drug that has not yet produced in commercial scale. Note: * Only NCE/Biological Product New Additional Indication and Posology - Non-Clinical & Clinical were evaluated through Committee of Safety-Efficacy evaluation and National Committee then continue with Committee of Quality Evaluation, and Committee of Product Information. *Others (Generic & variation) were evaluated with Committee of Quality Evaluation, and Committee of Product Information.	See https://www.pmda.go.jp/english/review-services/reviews/0001.html	Refer at MFDS website 1) Chemical: www.mfds.go.kr/eng/wpge/m_17/de011008l001.do 2) Biologicals: www.mfds.go.kr/eng/wpge/m_22/de011012l001.do 3) Herbal Medicines: www.mfds.go.kr/eng/wpge/m_23/de011013l001.do The flow is same but the organization (division in charge) has been changed afterwards	Disclosed. See DRGD Section B: Product Registration Process	A semi-electronic process is currently being used by FDA 1.Appointment, screening/pre-assessment (for completeness and compliance to format; not face-to-face) 2.Payment (online/bank transfer) 3.Queuing, Evaluation 4.Regulatory Decision 5.Releasing (FDA Circular No. 2020-026)	https://www.hsa.gov.sg/therapeutic-products/register/overview/overview	RTF (refuse to file) notification will be issued on Day 42 when a new drug application (NDA) or biologics license application (BLA) is deemed incomplete by the TFDA, the agency can decide not to review the application since 20-Aug 2019. And updated RTF checklist (Refuse to File) for NCE and Biological products (including Biosimilar) on 2-Nov-2021.	MS1: Pre-submission (year-plan and prioritization) MS2: Submission (100% e-submission) MS3: 1st round assessment (co-evaluation/screening) MS4: Consolidated response MS5: 2nd round assessment MS6: Expert advisory (NCE, NB – for expert meeting) (decision based on critical questions) MS7: Decision MS8: Post decision MS=Milestone GMP Clearance for drug product in parallel. BE study report review for new generic drugs in parallel.	1. Upon receiving a dossier, Drug Administration of Vietnam (under Ministry of Health) will organize to evaluate. Different parts will be independently evaluated by different experts/expert groups. + DAV releases DL if dossier is not enough + If dossier is passed, it'll be present in Advice Committee meeting for granting MA. 2. Drug Committee/ Advisory Council to review and conclude in visa meeting to reject or approve 3. Official announcement by Ministry of Health
	Review time	・CTA/supplementary CTA: 60WDs ・NDA: 200WDs ・Priority review: 130WDs ・Orphan drug with urgent clinical need: 70WDs ・Independent application for generics of domestic launched chemical AP: 200WDs ・Supplementary application for variation: 60WDs, supplementary application combined with several application items: 80WDs, and 200WDs for the case involved clinical data inspection and QC testing/inspection ・Drug generic name approval: 30WDs ・OTC eligibility review: 30WDs Additionally, NMPA issued Announcement on Provisionally Extending the Time Limit for Supplementary Dossiers for Drug Registration Application ([2022] No. 86) on Oct. 14, 2022, indicated that the time limit for supplementary dossiers shall be extended by 80 WDs, effected for the period of Oct.14 to Dec. 31, 2022.	NCE: 5-8 months Generic: 9-12 months	New drugs manufactured in India: 8-12 months New drugs imported to India: 12-18 months	Timeline of renewal registration for 8 hour for pure renewal (unwritten regulation) is removed in the BPOM online System because of an national incident of acute kidney injury due to ethylene glycol and diethylene glycol substances.	Review time change (80 percentile value) Priority review: 9.0 months (As of Mar. 2021) Standard review: 11.9 months (As of Mar. 2021)	1. FP: 90 working days 2. DMF: 120 working days (if inspection is required) / 90 working days (if inspection is not required) 3. Biologics: 115 working days (If there is no additional questions or request of additional documents from the MFDS)	See DRGD Section 10.3 Timeline For Product Registration Eg: NCE/NBE: 245 working days; Hybrid: 210 working days; Generics: 210 working days, etc. Shorter review timelines are targeted for different accelerated pathways. ・FRP Abbreviated review: 120 working days ・FRP Verification review: 90 working days ・Orphan drug: 120 working days	The updated Citizen's Charter 2022 (3rd Edition) provides a working timeline for new drug applications at 180 working days. With the new reliance scheme called "Facilitated Review Process" and "WHO Collaborative Review Procedure" in place, the timelines can now be as soon as 60 days. (FDA Circular No. 2022-004)	For therapeutic products Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE Aug 2022, TPB-GN-005-010 – TARGET PROCESSING TIMELINES. APPENDIX 5 TARGET PROCESSING TIMELINES Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Verification: 60 working days For Class 2 CTGTP Screening: 50 working days Evaluation: Full dossier: 270 working days Abridged: 180 working days Reference: HSA | Fees and turnaround time for CTGTP	NCE NDA & BLA standard review: 360 days Priority review: 240 days Abbreviated review: 180 days/120 days For the non-NCE NDA with efficacy & safety clinical data, the review timeline in TFDA/CDE is 300 days. For the non-NCE NDA without efficacy & safety clinical data, the review timeline in TFDA/CDE is 200 days.	Timeframe for approval of new drug (NCE) and new biologics is 220 working days Vaccine 280 working days (priority review 200 working days) Biologics 160 working days Generics and new generic 135 working days Generics follow monograph 95 working days WHO-PQ and SRA CRP 90 working days * Referred to Notification of Thai Food and Drug Administration Re: Guideline for Application of Registration and Amendment of Modern Medicines for Humans through the Referred Evaluation Results from the Collaborative Registration Procedure (CRP) (Feb 2023) (timeline MS2 to MS7 exclude Thai FDA stop clock)	within 12 months under normal scheme

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NDA Approval review	Priority review system	In new DRR (SAMR No.27), there are 4 accelerate pathways, including Breakthrough, Conditional Approval, Priority Review and Special Approval. To accelerate the entry of overseas new drugs urgently needed in clinical practice to China, first batch of "List of Overseas New Drugs Urgently Needed in Clinical Practice" was issued by NMPA&NHC in Nov. 2018. The list has been updated for three batches until 31st Dec,2020. The application of drugs in the list can be submitted directly in accordance with the Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs.	Usually no; except the following situations, 1. official request from Hospital Authority upon urgent situation. 2. there is a local unmet medical need of the product for communicable diseases or matters of public health importance (e.g. vaccine of recent epidemic outbreak)	Accelerated Review: New Drugs for a disease depending on severity, rarity, or prevalence and the availability or lack of alternative treatments – after assessing risk vs. benefit. Approval usually based on data from clinical trial where surrogate endpoint has been considered which are reasonably likely to predict clinical benefit, or a clinical endpoint. Post marketing trials shall be required to validate the anticipated clinical benefit – most common condition when accelerated approvals are granted If drug is intended for the treatment of: · serious or life-threatening condition · disease of special relevance in India · addresses unmet medical needs. Expeditious Review Clinical safety and efficacy have been established even if the drug has not completed normal clinical trial phases To treat a serious or life threatening or rare disease or condition; If approved, the drug would provide a significant advantage in terms of safety / efficacy Substantial reduction of a treatment-limiting adverse reaction and enhancement of patient compliance leading to an improvement in serious outcomes; Being developed for disaster / defence use in extraordinary situation, Orphan drug	Reliance system with 120 working days Refer to BPOM regulation No. 15 Year 2019 and Q&A of Reliance Mechanisms (2020). Refer to BPOM regulation No. 27 Year 2020 on 2nd amendment to Regulation of Head BPOM No. 24 Year 2017 and No. 13 Year 2021 on 3rd amendment to Regulation of Head BPOM No. 24 Year 2017 (Emergency Use Authorization)	A priority review system exists. Orphan drugs receive priority review automatically. New drugs not designated as orphan drugs that target other serious diseases, and are likely to contribute to the improvement of quality of healthcare may be designated as "non-orphan priority review product" based on overall evaluation of the seriousness of the target disease and medical usefulness of the drug. Designation is assigned based on the opinion of external experts if an application is submitted with an application for marketing approval. Legislation of "Early Conditional Approval System", SAKIGAKE designation and 'Early access for special-use drugs' were enacted in Dec 2019.	Yes Targeted area for the expedited review is as below. 1) Drugs used to treat or to prevent from life-threatening or serious diseases (including orphan drug, development stage orphan drug) that there is no existing treatment or aims to improve significantly in efficacy or safety than existing treatment options. 2) Drugs for prevention or treatment against the prevalence of biological terrorism or infectious diseases that may cause serious risks to public health 3) New drug developed by an innovation pharmaceutical company (a company designated by the Government)	Yes Priority Review Conditions, Product categories and Timelines as given in the DRGD Appendix 12 Priority Review	Currently, the FDA prioritizes the following types of applications: 1.Products to be manufactured exclusively for export 2.New drug products considered to be a major therapeutic advance 3.First five products of newly-licensed establishments 4.Products for government projects 5.Imported pre-qualified vaccines. Applicant must make a request for priority review, to be approved by FDA. When granted, application is put ahead of the queue; no explicit mention of reduction in processing timelines. With the on-going pandemic, any COVID-related product is a priority. In 2020, the FDA issues two Administrative Orders providing for alternative registration procedures. AO 2020-0044 adopts the Collaborative Procedure for WHO pre-qualified products, while AO 2020-0045 provides for the facilitated registration pathways such as the abridged reviews and verification reviews. Guidelines for implementing AO2020-0045 were issued in June 2022. (FDA Circular No. 2022-004) Guidelines for implementing AO2020-0044 were issued in October 2022. (FDA Circular No. 2022-009)	Priority review system or pathway is only applicable to product submitted via Abridged Evaluation (with 1 reference country approval); and meets the pre-defined criteria in the guide (unmet medical need, etc.). Grant of priority review is on case-by-case basis, at discretion of the Agency during Screening. Applicant will be notified at the point of acceptance of application, if request is granted.	Yes To improve the new drug accessibility to public and accelerate the new drug review and efficient utilize the review resource, TFDA announced or amend the several designations for sponsor utilization since Nov 2019 which include: 1.Designation Request of Medications for Pediatric Population or the Minority Patients with Serious Diseases 2.Streamlined review designation 3.Priority review designation 4.Accelerated Approval 5.Breakthrough Designation Reference: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=2984&id=32228 (no change comparing current regulation)	Yes Abbreviated review (2 categories: abridge assessment and reliance assessment) Expedited review (3 categories: accelerated review, fast track review, priority review)	**NDA Approval review** **Priority cases**: Yes. (Art. 33, Circular 08/2022/TT-BYT) 1. Cases qualified for accelerated evaluation pathway Drug registration dossiers shall be eligible for review under an accelerated evaluation pathway when satisfying one of the following conditions: a) Drugs on the list of orphan drugs issued by the Minister of Health. b) Drugs to support emergency requirements in national defence, security, prevention and combatting epidemics, mitigating consequences of natural disasters, calamities. c) Drugs produced domestically on new GMP-conforming manufacturing lines or on upgraded GMP-EU, GMP-PIC/S conforming or equivalent manufacturing lines within 18 months from the GMP certification date; d) Vaccines that are prequalified by WHO, vaccines used in national expanded immunization programs; d) Specialty drugs with special dosage form to which there are no more than 02 (two) similar drugs (of the same drug substance, the same dosage form, the same strength, same concentration) with a certificate of marketing registration still valid at the time of dossier submission, comprising: - Drugs for cancer treatment; - New generation of antivirals; - New generation of antimicrobials; - Drugs for the treatment of dengue fever, tuberculosis, malaria; - Immuno-suppressive drugs used in organ transplant. e) Drugs produced domestically, comprising: - Drugs produced under contract manufacturing or technology transfer arrangements being drugs for cancer treatment, vaccines, biologics, new generation of antivirals, new generation of antimicrobials, immunosuppressive drugs used in organ transplant. - Medicinal material drugs that are outcomes of satisfactory evaluated national, ministerial-level or provincial-level scientific and technology research grant, that are manufactured entirely from GACP domestically cultivated and harvested medicinal material sources. - New drugs produced domestically on which a clinical trial in Vietnam has been completed; g) New drugs (for cancer treatment, new generation antivirals, new generation antimicrobials), reference biologics; h) Brand name drugs produced under contract manufacturing or technology transfer arrangements in Vietnam. i) Drug products the manufacturer of which was changed leading to the issuance of a new marketing registration certificate according to the provision of point b clause 2 Article 55 of pharmaceutical law. 2. Cases eligible for dossier review under abbreviated evaluation pathway Drug registration dossiers shall be reviewed under an abbreviated evaluation pathway when satisfying all of the following conditions: a) Drugs manufactured at facilities that are periodically assessed by Drug Administration for GMP conformity. b) Drugs on the List of non-prescription drugs. c) Drugs that are not of modified release dosage form d) Drugs that are not for direct use on the eyes

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NDA Approval review	Orphan drug system	First "List of Rare Diseases" was issued by NHC/MOST/MIIT/NMPA/NATCM on May of 2018, including 121 rare diseases. In principle, the interval is not less than 2 years. There is no specific orphan drug review pathway but priority review pathway or special pathway. −Priority review pathway: Please refer to previous article "Priority review system" in new DRR. −Review time limit: 70WDs for the orphan drugs in urgent clinical needs that have been marketed overseas Additionally, CDE issued 2 guidelines regarding orphan drug review, CDE Notice on Technical Guidelines for Clinical Drug Development for Rare Diseases (No.71 in 2021) and CDE Notice on Statistical Guidelines for Clinical Research on Rare Disease Drugs (Trial) (No.33 in 2022)	No	Orphan Drug has been defined in Rule 2(x) of the NDCT Rules, 2019 as "a drug intended to treat a condition which affects not more than five lakh persons in India" No procedure or process outlined in NDCT Rules for Orphan Drug designation of a New Drug.	Orphan Drug system with 100 working days Refer to BPOM regulation No.15 Year 2019 Annex	Yes An orphan drug system exists. Designation criteria Number of patients -Less than 50,000 in Japan Medical need -There are no appropriate alternative drugs or treatment methods. -The efficacy and safety are expected to be outstanding and significantly greater than those of the existing drugs. Possibility of development -There is a theoretical ground for using the drug for the target disease and the development plan is acceptable. Incentives (1) Subsidy payment (2) Guidance and consultation on research and development activities (MHLW, PMDA, NIBIO). PMDA provides a priority consultation system. (3) Preferential tax treatment (4) Priority review (5) Extension of re-examination period The re-examination period for the drugs will be extended up to 10 years.	Yes. The orphan drug system exists. Designation criteria: -Prevalence is less than 20,000 in Korea -Drugs to treat diseases for which appropriate therapy and drugs have not been developed or have been significantly improved in terms of safety and/or efficacy, compared to existing alternative drugs - The validity of the development plan (including the clinical trial protocol) as an orphan drug in Korea is recognized. Also there is a designation system of "orphan drug on the development stage" for products that are in clinical phase in Korea (or products that are in non-clinical phase where have the possibility enter to clinical trials)	Yes The Malaysian Orphan Medicines Guideline was issued in December 2020. Appendix 13 Designation and Registration of Orphan Medicines	The Philippines has an Orphan Drug Law, where FDA shall: ·Prioritize the registration of orphan drugs ·Facilitate the issuance of Compassionate Special Permit for the restricted use of orphan drugs We are yet to see the implementation of this law.	No orphan drug designation available	Yes 23-Sep-2015 Orphan Drug Designation procedure was issued by TFDA, all ODD should submit technical documents according to application form and need to provide Orphan Drug safety efficacy tracking protocol execute after approval with periodical report to TFDA for review until NDA approval. Also provide Orphan Drug NDA registration schedule to TFDA.	No Even there is an orphan drug regulation in Thailand but the intention of this regulation is for the drug in need for rare & serious disease, low usage with no alternatives and face a problem of shortage nationwide. The drug has to be proposed by prescriber's association and be considered for enlisting in the list considered by Thai FDA Subcommittee. The regulatory requirement for generic drug is applied for orphan drug registration with the incentive of exemption of registration fee.	Yes The Ministry of Health already issued Circular 26/2019/TT-BYT on Orphan drug list, with following criteria: 1. A drug is considered to be included in the orphan drug list for prevention, diagnosis and treatment of a rare disease when it meets any of the following requirements: a) The drug is for prevention, diagnosis and treatment of a rare disease as stipulated by Minister of Health; b) The drug is indicated and classified as an orphan drug by one of the reference regulatory authorities. 2. A drug is considered to be included in the list of drugs not readily available is one for which in the Vietnam market there are no readily available other drugs that can substitute it, or one with documents proving significant quality, safety and efficacy benefits over other substitutable drugs in the local and international markets and falls under any of the following cases: a) A drug for prevention, diagnosis and treatment of diseases with low prevalence rate in a population at any point in time not exceeding 0.05% of the population and which is any of the following: a genetic, congenital, cancer, autoimmune, communicable, tropical infectious, or any other disease as decided by Minister of Health upon advice by the Professional Board formed by Minister of Health; b) Any vaccine, drug for diagnosis or prevention with estimated usage not exceeding 8,000 cases every year in Vietnam; c) A radioactive drug; a marker; d) A drug for which business activities do not generate sufficient profit to cover investment and marketing of the same in Vietnam market.

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NDA Approval review	Approval matters	The format of drug approval numbers for drugs manufactured domestically is: Guo Yao Zhun Zi H (Z, S) + 4-digit year number + 4-digit serial number. The format of drug approval numbers for drugs manufactured in China Hong Kong, Macau and Taiwan is: Guo Yao Zhun Zi H (Z, S) C + 4-digit year number + 4-digit serial number. The format of drug approval numbers for drugs manufactured overseas is: Guo Yao Zhun Zi H (Z, S) J + 4-digit year number + 4-digit serial number. ・In each case, H represents a chemical drug, Z represents a traditional Chinese medicine, and S represents a biological product. ・Drug approval numbers shall not change following post-marketing variations. ・Traditional Chinese medicines shall be subject to its provisions if any. Mandatory requirements since Dec.1 2020.	Current Certificate of Drug/ product registration form, the following information is described. ・ Company name/address ・ Name of Drug/product ・ Expiry date of the certificate	Data as required under Table 1 & Table 2 of the Second Schedule of NDCT Rules 2019	Refer to BPOM regulation No 24 year 2017 article 27, 28 & 29 : All submitted information in the electronic registration system are binding and subject to approval by the authority. Those are followings: 1.Information as master data 2.Administrative Documents 3.Quality Documents 4.Non-Clinical Documents 5.Clinical Documents 6.Product Information & Labelling	・Non-proprietary Name ・Brand name ・Ingredients and Contents or Nature ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product, Address, License/Accreditation Category, etc.	1. Product name 2. Classification number and classification (prescription drug or OTC) 3. Composition of the Drug Product 4. Appearance 5. Manufacturing method (Name and address of API manufacturing site should be written in the table) 6. Therapeutic Indications 7. Administration/dosage 8. Cautions for use 9. Packaging unit 10. Storage conditions and expiration date 11. Specification and test method 12. Manufacturing site 13. Conditions for Approval	All registration particulars. (Re: DRGD)	Brand Name Labels Priority Review FDA GMP Clearance	・Non-proprietary Name ・Brand name ・Ingredients and Contents or Nature ・Manufacturing Method ・Dosage and Administration ・Indications ・Storage Methods and Expiration Date ・Specifications and Test Method ・Name of the Manufacturing Site used to Manufacture the Product, Address, License/Accreditation Category ・Forensic status of drug	TFDA will issue approval letter with draft TPI after complete NDA review. TFDA will issue notification letter after TPI finalized within 15-30 days after approval letter issued. Applicants can prepare printed TPI and packaging material samples to collect the drug license after receiving License Collection Notification within 3 months. Drug product can be manufactured/imported after License collected.	Any changes require variation submission and approval is required.	MA covers the following information, ・Brand name ・Active substance and strengths/concentration ・Dosage form ・Package size ・Quality Specification ・Shelf-life * MA Number, Decision Number, issuance date, validity of MA ・Name & address of MAH ・Name & address of manufacturer ・Name & address of assembler, if any
	Other information concerning approval review	NMPA issued Announcement on Issuing Electronic Drug Registration Certificates ([2022] No. 83) on Oct.9, 2022, indicated that NMPA will issue electronic drug registration certificates from Nov.1, 2022. The scope of issuance includes the certificates of drug clinical trials, drug marketing authorization, drug renewal, drug supplementary application, protection of traditional Chinese medicines, imported medicinal herbs, chemical APIs, etc. and the certificates of Good Laboratory Practice approved or issued by the National Medical Products Administration (NMPA) from Nov 1, 2022. Electronic drug registration certificates shall have the same legal effect as paper registration certificates.	N/A	For vaccines CDL Kasauli is also engaged for CMC review	NCE should provide API Drug Master File or Internal Monograph as required in Part II Quality of Drug Substance or CEP of API with attachment & GMP Certificate of API's manufacturer. Approval of SMF should also be considered to get approval of registration number	-	-	There are four types of methods of evaluation 1. Full evaluation (standard pathway) 2. Full Evaluation (Conditional Registration) 3. Full Evaluation via Facilitated Regulatory Pathway (FRP) Abbreviated and Verification Review 4. Abridged review Special reviews include Conditional Registration for Pharmaceutical Products During Disaster, Priority Review and Orphan Drug pathways (as mentioned above)	There is a separate review team and processing timelines for New Drug Applications of Biological products.	Inclusion of Pandemic Special Access Route (PSAR) for supply of emergency Therapeutic Products to facilitate early access to critical novel vaccines, medicines and medical devices during a pandemic, such as the current COVID-19 pandemic. (https://www.hsa.gov.sg/hsa-psar	The application of new therapeutic, new combination, new administration, generic, biosimilar, new/change indication and follow first applicant to add/change indication need to of the addition of a new indication need to complete the Regulations for the Patent Linkage of Drugs Anne x II Declaration form of the status of pharmaceutical patents. The announcement announced on 14-Jan.-2020.	Reference country required: US, EU, UK, Switzerland, Japan, Canada, Australia	-

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NDA Pre-approval inspection	GCP inspection	Not mandatory. After the centralized acceptance since Dec.1st 2017, CDE entrust CFDI to conduct GCP on-site inspection during NDA review per CDE review needs. It is applicable for both domestic drug and import drug.	Not required	DCGI/CDSCO or State FDAs may conduct GCP on-site inspection. DCGI will issue instructions to the CDSCO officers/Inspectors to conduct the inspection identifying the clinical trial site/ facilities to be inspected. CDSCO issued GCP Inspection Checklist in Feb 2018	GCP inspection for local clinical study in Indonesia. GCP inspection for import product is not required.	The GCP on-site inspection is executed by PMDA for 2 or 4 medical institutions and applicants. In COVID-19, the reliability inspection is conducted remotely.	Yes. For all of the NDA that has clinical trials(Bioequivalence test included, usually domestic clinical trials).	Yes for local clinical studies. Details given in the. Malaysian Guideline For Good Clinical Practice (GCP) Inspection	GCP inspection for local clinical studies (if ever conducted) is not routinely done but may be done by FDA The FDA shall conduct inspections to ensure that the rights, safety, and well-being of study subjects have been protected, to ensure the integrity of the scientific data collected, and to assess adherence to GCP Principles and other applicable FDA regulations. (AO 2020-0010)	CT in Singapore Pre-marketing approval application inspections are usually done announced and apply to completed clinical trials. Criteria during GCP Inspections: (i) Protocol (ii) Applicable clinical trial and clinical research material regulations* (iii) ICH E6 (R2) Good Clinical Practice Guidelines (ICH E6 GCP) (iv) Applicable Sponsor / Contract Research Organization (CRO) / Site Standard Operating Procedures (SOPs) for clinical trials (CLINICAL TRIALS GUIDANCE GUIDANCE ON GCP COMPLIANCE INSPECTION FRAMEWORK GN-IOCTB-11 Rev. No. 003)	TFDA announced about GCP inspection process on 28-May-2020 and the implementation date is 1-July-2021 https://www.uqs.com.tw/tw/p/962/announcement--strengthening-the-plan-to-strengthen-the-link-between-gcp-verification-of-drug-clinical-trials-and-registration-and-review-of-new-drug-inspection	No requirement	N/A. Applicable for local clinical trials only. When local clinical trial is conducted, GCP inspection is carried out. (Article 10. Circular 29/2018/TT-BYT)

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NDA Pre-approval inspection	GMP inspection	The CDE shall decide whether or not to carry out drug registration development site inspection based on the risks, the innovativeness of the drug, and the previous inspection results of drug research institution. Where the CDE decides to initiate drug registration development site inspection, the CFDI shall be notified to organize and implement inspection during the review period, and the applicant shall be informed at the same time. The CFDI shall complete on-site inspection within the prescribed timelines and present related materials including inspection results and inspection conclusions to the CDE for comprehensive review. The CDE shall decide whether or not to carry out drug registration manufacturing site inspection based on the product under registration application, the process, facilities, previous inspection results and the risks Conduct during 40 WDs after acceptance and 40 WDs before complete the review. In order to clarify the principle, procedure, timeline and requirement for implementation of drug registration inspection, to specify the cohesion of drug registration manufacturing on-site inspection and pre-approval GMP inspection, CFDI issued Working Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) and Key Points and Determination Principle of Drug Registration Inspection (Pharmacology and Toxicology Study, Drug Clinical Trials, Pharmaceutical Development and Manufacturing Site) (for Trial Implementation) on Dec.20, 2021 and taken into effective since Jan. 1, 2022. Working Procedures for Initiating Drug Registration Inspection and Testing (for Trial Implementation) was issued by CDE on Dec.20, 2021 and taken into effective since Jan. 1, 2022.	For manufacturer with PIC/S GMP: Document inspection only, CPP/GMP certificate from source country accepted. For manufacturer without PIC/S GMP: DOH would conduct PIC/S inspection to the facilities before its product would be considered for registration in HK.	GMP inspection of Indian manufacturing units will be arranged before granting the manufacturing license and periodic review of the manufacturing unit. The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of manufacturing units outside India on need basis.	BPOM Regulation No. 7 Year 2019: For imported product: Based on evaluation of Site Master File, if necessary, desk inspection and GMP inspection site will be request by BPOM. GMP Inspection Report from PIC/S country will be evaluated and can be considered for waiving on inspection	GMP compliance inspections are mandatory requirements prior to seeking marketing approval. Application for GMP compliance inspections for all manufacturing sites listed in the application for marketing approval must be submitted to the GMP compliance inspection authority (PMDA or respective Prefectures) by each manufacturing site	Yes. For sites that has no MFDS inspection history. For sites of which there is MFDS inspection history, waiver period for on-site inspection is given. (5 years for non-sterile products, 3 years for sterile products). Also for non-sterile products, on-site inspection is replaced to desk-top assessment if the manufacturing site is located in the territory of PIC/s Participating Authority and has submitted an appropriate inspection report of the competent PIC/s Participating Authority. Currently, GMP inspections for foreign manufactures are conducted in one of the two methods: on-site inspection and remote assessment.	On-site inspection (both local and oversea) required unless exempted (e.g., inspected by a PIC/S participating authority or located in an ASEAN member country which have been inspected by the local HA). (Details given in Guidance Document Foreign GMP Inspection) Some flexibilities are provided during the COVID19 pandemic. Laboratory should get the GLP certification if applicable, and GLP inspection will be conducted if necessary.	Before submitting an NDA for imported products, applicants must first secure a foreign GMP certificate from FDA for each manufacturer involved in the final product. This is obtained either through desktop review (if PIC/S-GMP certified), or through on-site inspection (for non-PIC/S) For locally manufactured product, GMP certificate is issued through actual inspection.	Documentary evidence must be provided to certify that the manufacturer(s) complies with current applicable GMP standards. Applicants must submit a GMP certificate issued by a drug regulatory agency for all drug product manufacturing sites including, but not limited to, bulk product manufacturers, primary packagers and secondary packagers. If the drug product is manufactured by a new overseas drug product manufacturing site not previously registered with HSA before 1st April 2004, a GMP Conformity Assessment will be conducted by HSA. Thus, when applicable, applicants must also submit the application form to request for GMP Evidence Evaluation or for an Overseas GMP Audit with the required documents as stipulated in the Guidance Notes on GMP Conformity Assessment of an Overseas Manufacturer.	TFDA website for PMF for reference: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=417	Require GMP clearance for all manufacturing flow in P3 except Quality testing site. Site inspection might be required in case submitted document is insufficient.	- Normally, GMP certificate from source country is accepted. But according to Decree 54, (Article 96, clause 3), Inspection can be conducted in cases of: a) MFR has registration dossiers of drug product, drug substance which is modified, or suspected of untrue information, data. b) MFR has drug product which is concluded as level 1 of quality violation by MOH. c) MFR has submitted a dossier of requesting manufacture condition evaluation, but the dossier is concluded as not matching requirement of GMP by MOH. - Mutual recognition, acceptance of inspection, outcomes from pharmaceutical regulatory authorities with regard GMP compliance shall be applicable to: a) Manufacturers of countries on the MOH-issued list of countries with which Vietnam has international mutual recognition treaty regarding GMP inspection outcomes, ICH countries and Australia, except for the cases stipulated in clause 3 (above). b) Manufacturers belonging to ICH member countries, Australia and that are inspected and assessed as in conformity with Good manufacturing practice by US Food and Drug Administration, USFDA, European Union member countries, European Medicines Agency (EMA), Australia (Therapeutic Goods Administration, TGA), Japan (Pharmaceuticals and Medical Devices Agency, PMDA) or Canada (Health Canada), except for the cases stipulated under clause 3 of this Article (above).
	Other inspections	The revised China GLP (draft) was issued for public comments on Nov.21st 2018. NMPA can conduct an unannounced inspection for drugs and medical devices. The unannounced inspection refers to the supervision and inspection conducted in the process of research, development, manufacture, distribution and use of drugs and medical devices by the regulatory authority without advance notice.	GLP inspection and PV inspection are not required.	GLP audit shall be the part of GMP audit.	In the GMP inspection site, the Laboratory is inspected by NADFC. The Laboratory inspected following GLP requirements .	"Paper-based compliance inspections" are executed by PMDA to confirm whether the data attached to the NDA application accurately reflects the results of clinical trials, and other studies, and whether those were conducted in accordance with GCP, GLP and reliability standards.	Laboratory should get the GLP certification. GLP inspection will be conducted by MFDS if necessary and valid GLP certification may be issued.	Laboratory should get the GLP certification if applicable, and GLP inspection will be conducted if necessary.	Regular On-site inspection is conducted for all local establishments. On-site inspections of foreign manufacturers are tentatively restricted by COVID-19. (FDA Circular2020-020)	-	Business undertakings engaged in wholesaling, importing and exporting pharmaceuticals (including raw material), shall meet the standard of Western Pharmaceuticals Good Distribution Practice (GDP) Regulations, and shall obtain the western pharmaceuticals distribution license upon the inspection and approval from the central competent health authority. Raw material pharmaceutical need to comply with GDP Management scope before 31-Dec.-2022. TFDA website for GDP for reference: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=4071&id=40430 https://www.fda.gov.tw/TC//siteContent.aspx?sid=332 https://www.fda.gov.tw/TC/site.aspx?sid=4070&r=610624134	No requirement for GLP inspection	-

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Clinical trials	Necessary procedures to start clinical trials	IRB approval isn't mandatorily required by CDE before IND submission but should before starting the clinical trial. IND permission/IRB approval => HGRAC approval => start clinical trial	a. IRB approval b. If study medication is required to be imported, then application of clinical trial certificate (CTC) at Drug Office, Department of Health is required.	Clinical trial on new drug shall be initiated after approval by CDSCO and respective Institutional EC or an Independent EC. Application to CDSCO and EC can be made in parallel. Trials should also be registered with CTRI (Clinical Trial Registry of India; Indian Registry) before screening patients.	After receiving Clinical Trial Approval Letter from BPOM, the Clinical Study can be started. Refer to BPOM Regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	Need to submit Clinical Trail Notification (CTN) to PMDA. Contracts with clinical sites should be signed after 30 days from the date of CTN submission in case of 1st CTN, and 14 days in case of 2nd or later trial.	Regulatory approval: MFDS IND approval is required. Import investigational drug; It is necessary to be approved by MFDS in order to initiate the clinical trials. IRB approval is required at each investigational site.	Submission to NPRA and Research Review Committee (RRC) / Medical Research Ethics Committee (MREC) can be done in parallel. 1. Clinical Trial Import License (CTIL)/ Clinical Trial Exemption (CTX) application to NPRA2. Application to the relevant RRC/ MREC 2. Application to the relevant RRC/MREC After receiving the approval for each of these processes, the clinical trial can be started.	1.Secure a License to Operate (LTO) for CRO and/or Sponsor 2.Secure Clinical Trial Approval and Import License (from FDA) 3.In parallel secure IRB/EC from institution (Administrative Order No. 2020-0010)	Reference to: Clinical Trials Guidance Determination of whether a Clinical Trial requires Clinical Trial Authorization (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC) GN-IOCTB-01 Rev. No. 003. (1 Mar 2021) Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions GN-IOCTB-04 Rev. No. 004 (28 April 2021) For CTGTP: Chemistry, Manufacturing and Controls Requirements for Cell, Tissue or Gene Therapy Products for Clinical Trials and Product Registration (Appendix 8) Mar 2021. In addition to the above, a valid IRB approval is required prior to trial initiation as well.	1.TFDA approval and Import permit of IMP 2.IRB approval (IND in TFDA and IRB can be submitted parallel) 3.CTA signed with site 4.1st payment done to medical institution 5.IMP shipment to site (Import permit are needed if any lab kits and devices required)	Clinical trials not mandatory required for drug registration at Thai FDA	Procedures for registering a clinical trial 1. The owner of the drug for clinical trial shall submit an application for permission for clinical trial to the Administration of Science Technology and Training, the Ministry of Health, whether directly or by post. 2. The Administration of Science Technology and Training, the Ministry of Health shall verify legality of the application within 05 working days from the receipt of the application. If the application is not satisfactory, the applicant shall be instructed in writing to complete the application until it is satisfactory. 3. The applicant shall cooperate with the Administration of Science Technology and Training, the Ministry of Health in completing the application within 60 days from the date on which it is instructed in writing. After the aforementioned deadline, the application will be rejected. 4. Within 05 working days from the receipt of the satisfactory application, the Director of the Administration of Science Technology and Training, the Ministry of Health shall grant a written approval for clinical trial according to the Form No. 13 in the Appendix III hereof. If the application is rejected, it is required to respond and provide explanation in writing.
	Required data/ documents/ brochures to start clinical trials Are there any local requirements of specific data other than ICH-M3 or S6, for initiation of clinical trials?	No All the toxicity data is included in the IB.	For additional requirements per individual scenarios, please refer to Appendix I of the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test version Jun 2022), p.11-14.	Data required as per Second Schedule of NDCT Rules, 2019	Clinical Trial Documents consist of: UK-1 Form, Protocol, Investigator's Brochure, Informed Consent, Documents of trial drugs, Summary Protocol of Batch Production (for Vaccine and biological products). Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	No Generally necessary data and or documents are followed as per ICH requirements. In some instances, additional reproductive toxicity tests are requested prior to clinical trials.	There is no additional requirement other than ICH-M3	Yes CTIL/CTX Application: The necessary data / documents are covered in the latest edition of the Malaysian Guideline for Application of CTIL and CTX. Regulatory submissions are made in parallel with IRB submissions. IRB/IEC Application: Details of documents required for submission are available, e.g., for The Medical Research and Ethics Committee (MREC), the relevant information is available under the User Manual/Documents section in NMRR website (https://www.nmrr.gov.my).	FDA follows ICH Safety and Efficacy Guidelines, ICH GCP (Administrative Order No. 2020-0010)	The sponsor should submit the supporting documents (listed in Table 1) to HSA for CTA, CTN and CTC applications. Reference to Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions GN-IOCTB-04 Rev. No. 004, 28 Apr 2021	Yes Investigator Brochure is required for clinical trial approval.	Not applicable	An application for permission for clinical trial consists of: a) An application form b) Documents containing information about the drug (general information about the drug for clinical trial: name, ingredients, indications, physical and chemical properties, dosage form and other relevant information); pre-clinical trial documents; documents about the clinical trial in previous phases), prepared in Vietnamese or English language and accompanied by a summary made in Vietnamese language.

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Clinical trials	Required data/ documents/ brochures to start clinical trials Are there any local requirements of documents/brochures outside IND/CTA dossier?	Yes -CRF & ICF -Contract with site -IRB approval -Human genetic resource approval -Some sites require insurance certificate for the clinical trial -IMP Certificate of Analysis (Some sites require GMP certificate), and PI's CV are required.	For additional requirements per individual scenarios, please refer to Appendix I of the guidelines (Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test version Jun 2022), p.11-14.	Data required as per Second Schedule of NDCT Rules, 2019	Informed Consent to the patient Refer to BPOM regulation No. 21 Year 2015 about Procedure of Clinical Trial Approval	Yes Explanatory materials and consent form used for obtaining informed consent	Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). Insurance certificate is required prior to the start of the clinical trials.	Yes The Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption covers all the main requirements including Informed Consent Form. Other key guidelines for conducting clinical trials in Malaysia are: ·Malaysian Guideline for Good Clinical Practice ·Malaysian Guideline for Safety Reporting of Investigational Products ·Guidelines for Good Clinical Practice (GCP) Inspection ·Malaysian Guideline for Bioequivalence Inspection Malaysia Guideline for Phase 1 Unit Inspection and Accreditation Programme	·Application Form ·IP and ancillary supplies info ·Import license application ·Clinical Trial Protocol ·GCP Certificate and CV of Primary Investigators for each trial site ·Informed Consent Form ·Investigator's Brochure ·Pharmaceutical Data ·Labeling Materials (Administrative Order No. 2020-0010)	Yes • Informed Consent Form • Investigator's Brochure • Principal Investigator's CV • List of overseas sites (if applicable) • GMP certificates • COA for study batches of investigational product • CMC documents, if requested by HSA. Reference: GN-IOCTB-04 Rev. No. 004 REGULATORY REQUIREMENTS FOR NEW APPLICATIONS AND SUBSEQUENT SUBMISSIONS Ref: https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-04_new_and_subsequent_appl_28apr2021.pdf	Yes For bio-sample needed to send out overseas, infectious samples need the statement from central lab and the export permit. For the case authorized to CRO, the authorization letter from sponsor is required.	Material Transfer Agreement	Yes a) An application form b) Documents containing information about the drug for clinical trial: - Drug trial documents: composition, manufacturing process, quality standard and drug test report (in the case of a modern drug, herbal drug or traditional drug, it is required to have a drug test report of the state-owned drug-testing facility that complies with GLP or provider of drug/medicinal ingredient testing services that complies with GLP within its scope of operation or of the manufacture that complies with GMP; in the case of a vaccine, it is required to have a quality test report of the National Institute for Control of Vaccine and Biologicals or Certification of analysis in the case of a batch of vaccines and biologicals); - Documents about pre-clinical trial of the drug that needs to be tested: reports on pharmacological effects, toxicity, safety, proposed dose, administration route and directions for use; - Documents about the clinical trial in previous phases (if the trial facility applies for permission for clinical trial in the next phases and the drug is not exempt from clinical trial in previous phases). c) Legal documents about the drug for clinical trial: - A copy of the written approval for registration of the clinical trial granted by the Administration of Science Technology and Training, the Ministry of Health. - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the application form for permission for phase 4 clinical trial submitted by the competent pharmacy authority if the drug is requested to undergo phase 4 clinical trial; - Package insert of the drug licensed for free sale if the drug is requested to undergo phase 4 clinical trial; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the trial facility's certificate of eligibility for pharmacy business; - A confirmation of participation provided by the trial centers if a multicenter trial is conducted in Vietnam; - A certified true copy or a copy bearing the seal of the trial facility, produced together with the original for comparison of the written approval for participation in the trial granted by the People's Committee of the province or central-affiliated city if a field trial is conducted; - A clinical trial agreement between the organization/individual that has the drug for clinical trial and the provider of clinical trial services; between the organization/individual that has the drug for clinical trial and the trial assistance organization (if any). d) A clinical trial outline and its description: - A description of the clinical trial outline (Form No. 08 in the Appendix III hereof); - A Case Report Form (CRF); dd) Principal investigator's academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution; e) Participant information sheet and volunteer letter (Form No. 09 in the Appendix III hereof); g) A record on scientific and ethical assessment prepared by the internal Biomedical Ethics Committee; h) Label of the drug prescribed in the Circular 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health.
	Required data/ documents/ brochures to start clinical trials Document Language and acceptability of English documents	In Chinese	Documents in English. Patient information and patients consent form in both English and Chinese or in Chinese only.	Submission to CDSCO (Indian RA) in English only Patient Information Sheets, and ICF needs to be translated in vernacular languages for submission to Institutional/ independent ECs.	Indonesian or English	In principle, all documents must be in Japanese language.	The summary of the Korean (extract of the mail contents) and the original text (in English) should be submitted. The MFDS can require protocol and consent form translated in Korean in case when they need it.	Documents in English or Bahasa Melayu.	English. For those intended for study subjects, English and/or Filipino language	English	Only protocol synopsis and documents to subjects should be in Chinese.	Thai and/or English	Vietnamese or English language

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	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. Are there any conditional requirements to accept foreign data, for example proof of the similarity in PK/PD?	Yes Overseas clinical trial data should meet ICH GCP and support the evaluation of efficacy and safety of target indications If no ethnic sensitivity factors that influence the efficacy and safety based on PK/PD study, overseas clinical trial can be accepted.	Yes (for NCE products). Not required for generic products.	Provision of waiver for phase 3 local clinical trial under certain circumstances however, a Ph-III waiver comes along with a Ph-IV commitment.	Acceptable, if the clinical data following GCP and the result based on evaluation of safety and efficacy is good.	Yes Acceptable if the similarity in PK/PD is indicated.	Yes Foreign clinical data are acceptable if the similarity in PK/PD is indicated.	No	Yes Acceptable if the similarity in PK/PD is indicated.	Yes	Yes The following drug items are subject to a bridging study assessment: 1. New chemical entities (NCE); or 2. Genetically engineered drugs, vaccines, plasma derivatives of new molecular entities, and allergen extracts of new molecular entities	Yes	Yes, if: The clinical trials on drugs, the clinical data included in clinical documents must be in line with guidelines of ICH, Vietnam Ministry of Health or other organizations recognized by Vietnam (including guidelines of international organizations of which Vietnam is a member, guidelines of the reference regulatory authorities). If clinical trials are conducted before above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Clinical data (except for biologics similar to reference biologics and vaccines similar to the vaccines already licensed for marketing in Vietnam) shall cover information adequate for the analysis, the explanation of Asian ethnic factors on the safety and efficacy of the drug to allow extrapolation of the clinical data on Asian population according to the guidelines stipulated above or there must be data of bridging studies according to ICH-E5 for the extrapolation of clinical data on Asian population
Clinical trials	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. Please comment whether there are any requirements of local clinical study data for NDA application and local clinical study is necessary or not, especially for necessity of PK / healthy subject data and/or patient data in the country.	Chinese PK data is required by CDE to support China NDA/BLA, which can be generated prior or in parallel with phase 3 depending on the situation. Usually China joins global/regional MRCT, which indicates the consistency in drug response (i.e., efficacy and safety) between Chinese and overall population. If conditional approval is agreed by CDE, limited Chinese data can be used to support NDA/BLA and post-marketing commitment is required.	Not necessary	Under NDCT 2019, local clinical trial may not be required to be submitted If: (i) the new drug is approved and marketed in countries specified by the Central Licensing Authority under rule 101 and if no major unexpected serious adverse events have been reported; or (ii) the application is for import of a new drug for which the Central Licensing Authority had already granted permission to conduct a global clinical trial which is ongoing in India and in the meantime such new drug has been approved for marketing in a country specified under rule 101; and (iii) there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and (iv) the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the Central Licensing Authority: Provided that the Central Licensing Authority may relax this condition, where the drug is indicated in life threatening or serious diseases or diseases of special relevance to Indian health scenario or for a condition which is unmet need in India such as XDR tuberculosis, hepatitis C, H1N1, dengue, malaria, HIV, or for the rare diseases for which drugs are not available or available at a high cost or if it is an orphan drug. List of countries under rule 101 has not specified by the Central Licensing Authority as yet.	Generally, Indonesian patient's data requested which indicates similarity in drug response (i.e. Efficacy and safety) with foreign data for drug which is used for family planning programme and other drugs based on request from Authorized body, for example public health programme for TB, etc.	In principle, PK in healthy Japanese subject and Efficacy and Safety data in Japanese patients are requested.	Foreign data is acceptable. In principle, similarity in PK/PD between Korean and foreign data should be indicated. If the appropriate bridging data doesn't exist, bridging study is requested by MFDS for bridging data in Korean.	Not necessary	Local clinical trials for NDA approval of imported products are not mandatory.	Not necessary	NCE has to submit Bridging Study Evaluation package before or simultaneously with NDA. If BSE successfully waived and at least 2 of 10R countries has approved (2 CPP), foreign data package can be accepted and no need to perform domestic study. If a bridging study is required, local PK or clinical data is required.	Not necessary	Not necessary if: If clinical trials are conducted before above-mentioned regulations on drug development become available, the data from such trials shall be acceptable for the purpose of dossier evaluation. Clinical data (except for biologics similar to reference biologics and vaccines similar to the vaccines already licensed for marketing in Vietnam) shall cover information adequate for the analysis, the explanation of Asian ethnic factors on the safety and efficacy of the drug to allow extrapolation of the clinical data on Asian population according to the guidelines stipulated above or there must be data of bridging studies according to ICH-E5 for the extrapolation of clinical data on Asian population

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Clinical trials	Acceptability of overseas clinical data, and requirements of additional local clinical studies for domestic NDA application when foreign data is to be used. When requirement of the local subject data exists, please specify the required number (or rate) of local subjects in the pivotal clinical studies for NDA approval	In general, sample size needs to discuss with CDE at pre-IND communication. The total subjects' number depends on the trial design and the needs of statistics, of which Chinese subject number should meet the consistency evaluation with overall population in drug response. For drugs approved in overseas but not yet in China, and for rare diseases, CTW can be applicable. Furthermore, additional indication can be discussed with HA case-by-case.	Not specified.	N/A	Local clinical trial is needed for new drugs for family planning programme, TB drugs, and others drug based on request from Authorized body.	With the notification in December 2021, the limit on the required number of patients (1 year, 100 cases) was lifted for long-term administration data of Japanese in chronic diseases.	Not specified. Authority often requests statistically meaningful number of patients to be included even in the local study.	N/A	There is no required number of local subjects in clinical trials for NDA approval. For local Phase IV Clinical trials, 3000 patients, unless justified. (Administrative Order No. 2006-0021, Bureau Circular No. 5 s. 1997)	N/A. But in the HSA CTC application, applicant has to declare expected number of subjects to be enrolled from each site.	It is requested to show the consistency in drug response between Asia population and Caucasians in multi-national clinical trials. For this purpose, at least 15-20% of all subjects is hopefully to be Asian population. As for NDA approval, it was divided to two situations. Non-CPP: Early clinical development in Taiwan, Ph 1+ Ph 3 or Ph 2+ Ph 3. Taiwan patient No. for Ph1 study : ≧10, for Ph 2 study: ≧20, for Ph3 study: ≧80. One-CPP: One of Ph 1, Ph2 or Ph3 study in Taiwan. Taiwan patient No. for Ph1 study : ≧10, for Ph 2 study: ≧20 or 10%, for Ph3 study: ≧80 or 10%, or Multinational Ph3 study for US FDA and EMA registration purpose: total sample size ≧200 then Taiwan No. ≧30 or 5%, total sample size ＜200 then Taiwan No. ≧10. Two or more CPP: Clinical trials in Taiwan is not mandatory. However, there might be requested local study if the consistency in drug response between Asia population and Caucasians could not showed.	Not necessary	N/A
	Environment for conducting clinical trials Practical number of clinical centers or sites in the country. Please comment if there is any license system for clinical study site.	Drug clinical trials shall be conducted in properly filed clinical trial institutions with needed conditions. Vaccine clinical trials shall be carried out or organized by tertiary medical institutions or disease prevention and control institutions above the provincial level that meet the requirements prescribed by the NMPA and the National Health Commission.	Practicable no. of clinical study sites not specified; No license system for clinical study sites; however, the clinical study sites are usually university or government hospitals.	More than 1500 clinical trial sites	It is around 50 clinical centers.	Clinical trial can be initiated in many study sites. No license system for clinical study site.	All investigational sites must be certified by MFDS, there are 208 sites (DEC 2022). Since 25OCT2018, all samples in clinical trials should be tested in certified GCLP laboratories by MFDS. There are 177 GCLP laboratories (MAR 2022).	The ICR (Institute of Clinical Research) functions as the clinical research arm of the MoH. It has 33 branches located at major MOH hospitals (Hospital CRC) and National Cancer Institute.	Clinical trial can be initiated in a study site that is Philippine Health Research Ethics Board (PHREB)-accredited (ethics committee exists)	There are 13 public hospitals and 16 private hospitals which can conduct clinical trials.	All medical centers or teaching hospitals and specialized hospital are qualified to conduct clinical trials in Taiwan. It's around 128 centers/teaching hospitals	23 officially recognized sites (IRB/EC sites)	Practicable no. of clinical study sites not specified; No license system for clinical study sites; however, the clinical study sites are usually university or State hospitals.
	Environment for conducting clinical trials Installation of IRB system for clinical trials. Is there National IRB?	When the drug clinical trial application is approved, the sponsor shall formulate the corresponding drug clinical trial protocol and have it reviewed and approved by the ethics committee before carrying out the subsequent phase of clinical trial, and submit the corresponding protocol and supporting dossiers on the website of the CDE.	Yes An IRB for each cluster of hospitals.	Independent Ethical Committee (IEC) Institutional Ethics Committee No National IRB or Central EC For reviewing proposals of regulated clinical trials, all ECs needs to be registered at CDSCO (Indian Regulatory Authority) EC registration need to be renewed once every five year	There is National IRB system	Institutional IRB.	IRB should be installed in each investigational site. The central IRB (joint IRB) is also available since JUL 2022.	No But a Central Ethics Committee, called the Medical Research and Ethics Committee (MREC), reviews and approves all clinical trials to be conducted at all MOH hospitals as well as institutions without a Local Ethics Committee.	Ethics committee of a clinical trial site should be accredited by PHREB.	Singapore has 3 clusters of public hospitals. 1 cluster is under NHG DSRB (National Healthcare Group Domain-Specific Review Board), NUHS Group and the SingHealth CIRB (Centralised Institutional Review Board). For private hospitals, they have their own IRB/EC	C-IRB (jointed IRB review) system led by the TFDA has been adopted since 2013. Systems to reduce review periods and to prevent the duplication of inquiries and inconsistencies between IRBs have been adopted. Deliberations are carried out in turn by the 7 major facilities. After c-IRB, the sponsor can receive abbreviated review by each IRB using the results of the c-IRB.	Increasing number of IRB that adopt National IRB submission. Previously, it can submit directly to local IRB.	Yes There are EC both at the Site and on the health authority level

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Clinical trials	Environment for conducting clinical trials How is the actual subject enrollment situation? Are there any supportive system for patient enrollment, such as clinical trial network?	There is intensely competitive between different clinical trials for subject enrollment. Some regional clinical trial networks are established spontaneously by researchers.	The government's policy is to recommend the implementation of clinical trials regardless of the phases from the perspective of industrial development. There are 2 major clinical research centers under the umbrellas of 2 large medical universities, and they are participating in more than 1,000 multinational clinical trials. The Phase 1 Clinical Trial Centre of CUHK and the Phase 1 Clinical Trial Centre of HKU started operations in December 2013 and the 1st quarter of 2014, respectively. Data from clinical trials implemented in accordance with CFDA standards is accepted by the CFDA at trial implementing facilities certified by the CFDA (Prince of Wales Hospital, Queen Mary Hospital, the Hong Kong Eye Hospital and Hong Kong Sanatorium and Hospital's oncology department).	Regulatory environment very conducive for clinical trials Single step review process by Regulators New rules are clear and streamlined Over 20 Subject Expert Committees support the CDSCO Approval timelines is < 90 days Responsibility of ECs strengthened Safety reporting and compensation regulations are very clear Subject enrollment is relatively faster given the population size of the country	Unknown	While the environment of clinical trial is improving, the number of the patients enrolled per institute still remains low, and, therefore, the relatively high clinical trial cost in Japan is noteworthy. Clinical trial networks have been established to improve patient enrollment. However, except for the pediatric or rare disease areas, the general engagement and utility of such networks are minimal.	It depends on the situations of target diseases or investigational sites. In general, the subjects are recruited in good manner.	Patient enrollment can be enhanced further. Clinical Research Malaysia supports clinical research in Malaysia.	Clinical trials in the country must be conducted following ICH GCP guidelines.	HSA has set up an Innovation Office in April 2018 to provide a conducive regulatory environment that supports the development of the biomedical sector, by providing scientific and regulatory advice for early stage clinical development of innovative therapeutic products intended for product registration in Singapore.	There are 14 TCTC. The enrollment per site varied by PI and site. There are less referral among the study and non-study sites	In most cases, participations in multinational clinical trials are from Phase 3. Inter-facility clinical trial network has been established	Participations in multinational clinical trials are possible. Local regulations are referring to the guidelines of ICH, WHO, Vietnam Ministry of Health or other organizations recognized by Vietnam (Source: Article 19 Circular 29/2018/TT-BYT)
	Environment for conducting clinical trials Prevalence of GCP in clinical centers	GCP is observed in all clinical sites. See new GCP (2020 No.57) which was effect since Jul.1st for details.	Yes	GCP, GLP and GMP is mandatory for all clinical trials. However, there is a need for upgrading GMP.	GCP is observed in all clinical studies	GCP is observed in all clinical sites.	GCP is mandatory. Regulatory authority often conduct an inspection of site to verify compliance to GCP	GCP is observed in all clinical study sites. (GCP is required 100% clinical site in Malaysia). Authority conducts site inspections to verify compliance to GCP.	GCP is observed in all clinical sites. Part of the licensing requirements for CROs and Sponsors is compliance to GCP. This is verified during inspection. Likewise, inspection of sites during clinical trials is conducted to verify compliance to GCP.	GCP is observed in all clinical studies	GCP implementation in all clinical trials is mandatory since 1997. TFDA has officially become the Regulatory Member of ICH on June, 2018.	A must	Regulated entities of GCP principles 1 Every trial facility shall conduct the clinical trial according to the approved clinical trial outline and GCP guidelines. 2. DAV shall inspect the site and classify GCP compliance of the local trial facility. MOH shall publish on its portal the GCP-certified trial facilities (Source: Article 7& 11; Circular 29/2018/TT-BYT)
	Environment for conducting clinical trials Number of investigators who will conduct or participate in the clinical studies.	Uncountable number of physicians in China. Additionally, in 2019, the number of drug clinical trials in China exceeded 1,600, a more than 20-fold increase from less than a decade ago. The number of clinical trial sites in China has also increased steadily over recent years, growing from less than 400 in 2015 to more than 1,000 in 2020, mirroring to some extent the increased number of clinical trials Sponsors are also inevitably attracted to leading clinical trial sites when choosing a site, with little willingness to consider other sites.	Yes	Large pool of trained Investigators and treatment-naïve patients in diverse therapeutic areas.	Investigator must have GCP training before the trial and understand the protocol comprehensively in order to conduct the trial in accordance to GCP.	Large number of physicians in Japan	Uncountable, lots of investigators in Korea. Mandatory educational system exists in Korea.	Since the introduction of the first edition of the Malaysian GCP in 1999 until 2018, more than 12,000 healthcare professionals and researchers have been GCP-trained and certified. (GCP 4th Edition)	Applicants are required to submit the CV of Primary Investigators for each trial site	No information	No data for the number of investigators. The physician who is working on qualified clinical site would be able to conduct/participate in the clinical studies. However, all investigator should meet TFDA's qualification, including required GCP & Ethical training etc.	No information (Beware of USFDA blacklist)	All investigators must possess appropriate qualifications, training, and experience. All investigators involved in the trial must have had formal training in good clinical practices (GCPs), and submit proof that a GCPs course has been completed. Principal investigator's academic résumé and copy of the certificate of completion of GCP training course which is issued by the Ministry of Health or GCP training institution shall be submitted in the application for permission for clinical trial. (Source: Article 19.2.dd. of Circular 29/2018/TT-BYT)

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Clinical trials	Investigational drug Condition of customs procedure.	The management of drugs for clinical trials shall conform to the relevant requirements of the GCP. As IND approval system changed to implied permission system, clinical trial notice letter is issued by CDE instead of CTA approval letter, which can be used for Customs procedures and clearance.	Application of Import License based on the approved CTC.	· Permission to import of investigational product shall be obtained by applying for a test license (import license). The application should be made in Form CT-16 with applicable fee.	Sponsor request to import unregistered product was to BPOM. Approval letter for Importation from BPOM is used for release product in the customs.	-	After receiving IND approval from the Ministry of Food and Drug Safety, a standard customs clearance report should be completed and approved by the Korea Pharmaceutical Traders Association.	Clinical trial import license and proper clearance required.	For the importation of each investigational drug product and ancillary materials, an import license is required. This is issued by together with the clinical trial approval valid for three years, and can be used repeatedly within the validity. (Administrative Order No. 2020-0010)	Reference to CLINICAL TRIALS GUIDANCE CLINICAL RESEARCH MATERIALS GN-IOCTB-03 Rev. No. 002, 1 Mar 2021	The import permit is issued by TFDA and Customs will allow investigational product import into Taiwan within the quantity on the import permit.	Condition of customs procedure - import license, CoA, Air waybill, invoice, License Per Invoice, National Single Window	MOH's DAV is responsible for authorizing the import and export of drugs in Vietnam. According to these sources, IPs for use in clinical trials are categorized as finished drugs without registration numbers. Once the MOH approves the clinical trial dossier, an import permit application must be submitted to the MOH's DAV for approval of the IP in the quantity specified in the clinical protocol. The import permit is valid for one (1) year. (Source: Article 94.1 of Pharmaceutical Law No.105)
	Investigational drug Requirements of Investigational drug labeling and its language.	Yes (in Chinese) Requirements include: 1) Indicate "only used for clinical trial". 2) For investigational drugs used in IMCT, sponsor name, trial number, kit number, dosage and administration, only used for clinical trial, dosage form, administration way, strength, batch number, storage condition, expiry date etc. need to be indicated in the label.	IP name: Strength, dosage, storage condition, manufacturer - English or English and Chinese	· "For Clinical Trials only" · Name or a code number of the study · Name and address of the Investigator · Subject's identification code · Name and Address of the importer	In Indonesia language for clinical trial in Indonesia. In Clinical trial Multicenter / country English language is acceptable.	Yes Investigational drug label written by Japanese is needed	Yes Korean investigational drug label is required and detailed contents are followed; 1. "For clinical trial only" 2. The name of investigational drugs or identification marking (in case of blind design, both study drug and comparator should be indicated in the IP label), if necessary, formulation, administration route, quantity, assay of active ingredient or potency can be included in the label. 3. The lot number or code number 4. Name, address and telephone number of business/person who received the IND approval 5. The expiry period 6. The storage condition 7. "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects. 8. Reference code (clinical trial can be identified) 9. Subject identification number, treatment number, visit number. 10. Name of Investigator (if necessary) 11. directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product)	Yes The labelling requirements should be in accordance with Malaysian Guideline for Application of CTIL & CTX, Appendix E (Labelling Requirements). Language in Bahasa Melayu or English.	Yes In English. Note that importation of investigational drug product requires an import permit.	Reference to CLINICAL TRIALS GUIDANCE LABELLING OF INVESTIGATIONAL AND AUXILIARY PRODUCTS IN CLINICAL TRIALS GN-IOCTB-07 Rev. No. 004, 1 Mar 2021. In English	Yes Label has to be prepared in traditional Chinese under PIC/S GMP regulation.	Yes Require product name or random number/subject no., dosage, amount, manufacturer, expiry date and the content of 'this product is used for clinical trial only' in Thai. Comprehensive list. (1) Non-proprietary name or drug code including strengths of active substance(s) (2) Study number and/or study title (3) Batch number (4) In case of self-administration drug, e.g. home medication, etc., Thai or English instruction on how to use drug, which is understandable by subjects, should be provided (5) Name and address of the sponsor (6) Expiry date or retest date. (7) Storage condition (8) Indicate the sentence "for trial use only" in Thai *The auxiliary label that utilizes locally (by institution/investigational sites) must be submitted for approval by Thai FDA as well.*	Yes IP must be clearly labeled with the wording: "Products used for clinical trials. Use for other purposes is prohibited." A sample IP with the label in the smallest packed unit must also be included in the clinical trial dossier. Label of the drug shall be according to the Labelling Circular 01/2018/TT-BYT (Source: Article 19.2.h. Circular 29/2018/TT-BYT)

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Clinical trials	Investigational drug Acceptability of the use of domestically unapproved drug as comparator.	Yes For biologics, branded biologics that marketed abroad and IND approved domestically are acceptable to be one-time imported and used as comparator. For chemical drugs or APIs that marketed abroad are acceptable to be one-time imported and used as comparator to evaluate the quality and efficacy consistency of generic drugs	Not specified.	Approvals are granted case to case basis, mostly approved comparator is preferred	We can't use domestically unapproved drug as comparator. Comparator can be imported using special access scheme (SAS) path	Yes	It is possible to use if the unapproved drug is the international standard drug. It is recommended to have a Consultation with the MFDS in advance.	Yes Details given in Malaysian Guideline for Application of Clinical Trial Import Licence and Clinical Trial Exemption.	Yes the guideline does not define restrictions on the comparator drugs. For instance, the issued List of Comparator/ Reference Drug Products for BA/BE studies include unregistered drugs.	The unapproved drug can be used as a comparator as long as its protocol and CTC/CTA/CTN have been approved. CLINICAL TRIALS GUIDANCE CLINICAL RESEARCH MATERIALS GN-IOCTB-03 Rev. No. 002	Yes It is possible to use as IMP	No Not accept.	Yes For use as reference standards/comparator drug in bioequivalence studies; if it is a new drug, it shall be used exclusively for the study according to the already approved protocol under clause 1 Article 100 of Pharmaceutical law. (Source: Article 73.1.b of Decree 54)
	Availability of the support from multi-national CRO	Yes	Yes (domestic and multi-national companies).	Most of the top multinational CROs have full-service operations in India. In addition there are many Indian CROs.	Multi-national CRO is available in Indonesia	Yes Multi-regional CRO is available in Japan	Yes Multi-national CRO is available and local CROs are also available to support the clinical trials.	Yes International CROs include: https://ichgcp.net/cro-list/country/malaysia •Quintiles •PAREXEL •IQVIA •INC (formerly MDS) •Covance •Pharmanet •PPDi •The George Institute for International Health •Novotech Locally incorporated CROs include Info Kinetics Sdn Bhd	Yes Multi-national CROs are present in the country.	Yes Available	Yes There are around 34 CRO in Taiwan and over 12 multi-national CRO established branch office in Taiwan. There are less local CROs in Taiwan.	Yes There are many international CRO in Thailand	Yes
	Export of biological sample derived from subjects	According to the regulation, if export biological samples, getting the permission from IRB, HGRAC's approval is required as per based on "Human Genetic Resource Interim Management Measures" In practice, need to have sufficient rationale to get HGRAC's approval to export biological sample.	It is possible to export biological samples.	Allowed	There are restrictions on the export of biological samples from subjects (Ministry of Health Regulation No, 85 Year 2020). Application for the export of biological samples must be made to the Ministry of Health.	Yes It is possible to export biological samples if it is included in the signed informed consent document.	Yes It is possible to export biological samples.	Yes It is possible to export biological samples.	Yes It is possible to export biological samples.	Yes It is possible to export biological samples if the importing country's conditions are met. Meeting the conditions of the importing country is the responsibility of the applicant. An export license is not required from HSA for shipping of biological samples for testing overseas. Clinical Trials Guidance Regulatory Requirements for New Applications and Subsequent Submissions GN-IOCTB-04 Rev. No. 004, 28 Apr 2021 Additional considerations: HBRA guidance must be fulfilled as necessary, especially if biological samples for future research are involved. Source: MOH | Human Biomedical Research Act.	Yes It is possible (okay) to export biological samples and required to apply for export permit	Yes It is possible to export MTA may be required by IRB.	Yes It is possible to export.

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Clinical trials	Adverse reaction reporting during clinical trial	Adopt to ICH E2A, E2B(R3) -SUSAR occurred during the clinical trial in China and outside of China should be reported to CDE. -For fatal or life-threatening SUSAR, sponsor needs to report to CDE within 7 days after initial receiving SUSAR; for non-fatal or life-threatening SUSAR, sponsor can report to CDE within 15 days after initial receiving SUSAR. -If Chinese translation can't be prepared well, sponsor can submit the English report to CDE firstly, then Chinese report can be submitted in the next 15 days.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days; submit report in 8 additional calendar days - Others: 15 calendar days NSAE and serious expected adverse events: - Brief summary at the end of trial	Reference: Third Schedule – Post Market Assessment (NDCT Rules, 2019) Any report of the serious adverse event, after due analysis shall be forwarded by the Investigator and Sponsor to the Central Licencing Authority, the Chairperson of the ethics committee and the head of the institution where the trial has been conducted, within fourteen days of knowledge of occurrence of the serious adverse event as specified in Table 5 of Third Schedule In case of injury or death occurring to the trial subject, the sponsor (whether a pharmaceutical company or an institution) or his representative or the investigator or the institution or centre where the study was conducted, as the case may be, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in accordance with the procedure as prescribed in Chapter VI of NDCT Rules 2019	Additional information: Sponsor should report serious adverse event in clinical trial which have life threatening within 7 working days start from the first time known the event, and following 8 working days to complete the report.	Cases of death by unknown, adverse events have to be reported to PMDA within 7 days. Cases of death by known adverse event and unknown serious adverse event have to be reported within 15 days.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by as complete a report as possible within 8 additional calendar days - Others: no later than 15 calendar days	Death or possibly leading to death SAEs within 7 days, other SAEs within 15 days.	Serious and unexpected adverse events - Fatal/life threatening: no later than 7 calendar days; complete report within 8 additional calendar days - Others: no later than 15 calendar days For expected ADRs, reporting is part of the annual progress report. (Administrative Order No. 2020-0010)	For fatal or life-threatening USADRs, local sponsors must submit the initial report as soon as possible and no later than 7 calendar days, with the next follow-up report within 8 calendar days of the initial report. Subsequent follow-up reports should be submitted in a timely manner as they become available. For other USADRs, local sponsors must submit the initial report as soon as possible and no later than 15 calendar days. Subsequent follow-up reports are to be submitted in a timely manner as they become available. Guidance: CLINICAL TRIALS GUIDANCE EXPEDITED SAFETY REPORTING REQUIREMENTS FOR CLINICAL TRIALS GN-IOCTB-10 Rev. No. 002, 1 Mar 2021	SUSAR: report to Authority within 7 days for death and life threatening case, within 15 days for other cause. It is same as international rule. DSUR need to submit TFDA which was announced by TFDA Official Letter No. 1091403101 dated July 1, 2020	To FDA: Only Local SUSAR, death or life-threatening related to study product within 7 days, other local SUSAR within 15 days (from sponsor awareness) To site IRB/EC: Death or life-threatening within 7 days, other SAE within 15 days (FERCIT)	Acc.to Decision 62/QD-K2DT/ 2017: CRO, and other relevant organization, person have responsibility to report AEs/ SAEs: a) AE/SAE occurred in VN territory: - For death or life-threatening SAE: urgently reported within 7 working days when having SAE information. - Other SAE: within 15 working days when having SAE information. - In case of additional information on medical happening of SAE, or happening of patients with SAE, or change of relationship between SAE and investigational product: within 15 working days since the day having additional information. b) AE/SAE occurred outside VN territory (VN is one of countries in multi-national CT): All SAEs which makes trial protocol change, or make trial pause in one country member should be reported to Administration of Science Technology and Training- MOH, EC of MOH, National center of ADR and drug information as CIOMS form or appendix 1 of the Decision 62. - Timeline of report: not more than 15 working days since the day having decision on trial protocol change, or trial pause.
	GCP site inspection	Yes Clinical trial inspection was conducted based on the review needs.	Accredited to the sites by separate parties.	Required	BPOM will do GCP site inspection during clinical trial	Yes After NDA, PMDA inspects the applicant and 2-4 medical institutions based on GCP.	Yes, by MFDS	Yes	Yes The authority inspects the applicant and medical institutions based on GCP.	Yes Will be conducted by the HSA Clinical Trial Branch, on locally conducted clinical trials.	Yes TFDA request GCP on site inspection for TW NDA registration purpose studies after CSR is submitted. However, effective from July 2021, for NME, the timing of GCP inspection will be trigger by NDA submission, For other than NME, the timing is still be trigger by CSR submission as the current practice. For oversea GCP inspection, TFDA and industries are still under discussion.	Yes	Yes (Article 10, C#29/2018/TT-BYT) GCP inspection is limited to domestic clinical site only.

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Manu -facturing	Acceptance test for Import drug	Specifications and test methods are set according to Chinese Pharmacopeia and product own specification	Based on the approved particulars.	Acceptance tests are conducted at the time of commercial imports.	Specification and test methods are following Indonesian Pharmacopeia, USP/NF, BP, EP, JP.	Specifications and test methods are to be set according to JP.	Specification and test methods are usually set in accordance with official compendium or registered in-house specifications.	Both compendial and non-compendial specifications are accepted.	Specifications and test methods are set according to pharmacopeia, or by companies supported with appropriate validation documents (Administrative Order 2013-0021)	To be tested according to approved specifications & test methods	There is no need to have acceptance test in Taiwan except for vaccine, toxins, and plasma produced products. TFDA will provide certification seal after TFDA QC acceptance test. TFDA will issue product releasing certificates and provide i serial sealing label on the individual products. Need to provide sample of NCE, new compound medicine, and first API to TFDA for future inspection prior to be on market, except radiopharmaceutical drugs, cell-based preparation and bio products needed to be tested.	Both compendial and non-compendial method are acceptable	Yes With regard to vaccines, antibody containing sera, blood derivatives and plasma from human: The registrant must collect samples for quality control testing at the National institute for control of vaccines and biologics. The registrant must submit Test certificate, test standard and method, certified by the National institute for control of vaccines and biologics as part of the registration dossier
	Pharmacopeia	All import drugs and domestic drugs should follow Chinese Pharmacopeia. ChP2020 will be effect since Dec.30, 2020	BP, USP, EP and JP. In-house specification for NCE is also accepted by DOH.	If a DP/DS is official in the Indian Pharmacopeia (IP) than must conform to IP if not official in IP than BP/USP/EU Pharmacopeia standards are to be followed	Standard Pharmacopeia: Indonesian Pharmacopeia Other accepted Pharmacopeia: USP/NF, BP, EP, JP	JP (Japanese Pharmacopeia)	Standard: KP Accepted: JP, Ph. Eur (EP), USP (NF), BP, Deutsches Arzneibuch, Pharmacipee Francaise	The main pharmacopeia references are BP and USP. Others are JP and EP	The FDA recognizes USP-NF, official Homeopathic, Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), BP, EP, JP, Indian Pharmacopoeia, and any national compendium or any supplement to any of them (Republic Act No. 9711)	Pharmacopeias accepted by HSA are Ph. Eur., USP, BP, and JP	USP/NF, EP, JP, BP and ChP. are all acceptable.	Standard Pharmacopoeia: USP 39/ NF 34 and supplements, BP 2016 volume 1-5, the fifth edition of IP and supplements, the eighth edition of EP and supplements plus updated revision, JP 17th edition*, and Thai-pharmacopoeia II volume I part 1 and supplements. In addition, the updated version of standard pharmacopoeia as announced is accepted. * effective in February 2020	Standard: Vietnam Pharmacopoeia Reference (USP/NF, JP, EP, BP, IP) Pharmaceutical business establishments and drug preparing facilities can apply Vietnam's pharmacopeia or one of the following reference pharmacopeias: European, British, United States, International, and Japanese; (Source: Article 4 Circular 11/2018/TT-BYT)
	GMP system What is current GMP requirements?	-Chinese GMP 2010 version (MOH order 79) -According to revised China DAL, there will be no GMP certificating and relevant requirements will be included in the qualification of drug manufacturing license.	PIC/S has been adopted for local manufacturer and overseas manufacturer.	Indian GMP as outlined in Schedule M of DRUGS AND COSMETICS RULES, 1945. GMP was proposed to be upgraded but is awaiting finalization.	Indonesian GMP, PIC/S GMP & WHO GMP requirements	Japan has been a member of PIC/S GMP since July 2014.	PIC/S GMP requirements	PIC/S	PIC/S GMP is the standard used (Administrative Order No. 2012-0008)	PIC/S GMP requirements	TFDA announced on Jan. 2020 that the APIs for exportation only should be mandated to fulfill GMP requirements from Jan. 2022. Amendments of PIC/S GMP application forms and checking list for foreign manufacturing sites were announced on Sep 28th, 2021 to accommodate the updates of PIC/S GMP standard. Please refer to TFDA website https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=417&chk=9e77d38c-4b40-4e38-839f-d035268b9653&param=pn%3d1%26sid%3d301	Thai FDA is PIC/s country member effective from 1 Aug 2016.	**Current GMP requirements (**Art. 3 in 35/2018 revised by Circular 12/2022**)** 3. Manufacturers follow WHO-GMP, PICs-GMP or EU GMP standards & other GMP principles and standards equivalent to EU-GMP principles and standards promulgated by pharmaceutical management agencies of SRA countries. 4. Document updating GMP principles and standards: a) In case the World Health Organization amends and supplements the principles and standards of Good Manufacturing Practice for drugs and drug raw materials (hereinafter referred to as updated documents) specified at Points a and b; Clause 1 of this Article, within 3 months from the date on which the updated documents are published on the Web Portal of the World Health Organization; The Drug Administration of Vietnam or the Administration of Traditional Medicine and Pharmacy according to their assigned management capacity, organize translations and publish the revised and supplemented content on the website of the Ministry of Health for relevant parties to search, update and execute; b) In the case of the Pharmaceutical Inspection Cooperation System (PIC/S) or the European Union has updated documents specified at Points c and d, Clause 1 of this Article, and those documents have not been posted on the Portal of the Ministry of Health and the website of the Drug Administration of Vietnam, the manufacturer of drugs and medicinal ingredients that implements the application is responsible for translating and certifying the translation in accordance with the law on notarization and certification to submit it to the Drug Administration of Vietnam. Within 10 days from the date of receipt of the notarized and certified translation sent by the manufacturer of the drug or medicinal ingredient, the Drug Administration of Vietnam shall review, amend, and post it on the Portal of the Ministry of Health and the website of the Drug Administration of Vietnam. For foreign manufacturers having drugs registered for marketing in Vietnam: must submit GMP certificate from country of origin. Mutual recognition, acceptance of inspection, audit outcomes from pharmaceutical regulatory authorities with regard GMP compliance shall be applicable to: a) Manufacturers of countries on the MOH-issued list of countries with which Vietnam has international mutual recognition treaty regarding GMP inspection outcomes, ICH countries and Australia. b) Manufacturers belonging to ICH member countries, Australia and that are inspected and assessed as in conformity with GMP by USFDA, EMA, Australia TGA, Japan PMDA or Canada. (Source: Article 96, Decree 54)

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Manu -facturing	GMP system Please describe GMP evaluation process by the authorities.	According to new DRR, ・The CDE shall decide whether or not to carry out drug registration development site inspection based on the risks, the innovativeness of the drug, and the previous inspection results of drug research institution. ・The CDE shall decide whether or not to carry out drug registration manufacturing site inspection based on the product under registration application, the process, facilities, previous inspection results and the risks. ・The principles, procedures, timelines and requirements for initiating drug registration inspection shall be formulated and published by the CDE; the principles, procedures, timelines and requirements of implementing drug registration inspection shall be formulated and published by the CFDI. In order to clarify the principle, procedure, timeline and requirement for implementation of drug registration inspection, to specify the cohesion of drug registration manufacturing on-site inspection and pre-approval GMP inspection, CFDI issued Working Procedure for Drug Registration Inspection (for Trial Implementation) and Working Procedure of Cohesion of Drug Registration Manufacturing On-site Inspection and Pre-marketing GMP Inspection (for Trial Implementation) and Key Points and Determination Principle of Drug Registration Inspection (Pharmacology and Toxicology Study, Drug Clinical Trials, Pharmaceutical Development and Manufacturing Site) (for Trial Implementation) on Dec.20, 2021 and taken into effective since Jan. 1, 2022	For overseas manufacturer, inspection is usually not required if the manufacturer complies with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP standards. For local manufacturer or manufacturer without PIC/S GMP certification, an inspection by pharmacist inspector will be conducted at the company's premises within 2 weeks from the submission of a new application. The application will be considered by the committee. If approved, a license valid for 1 year will be granted.	GMP inspection will be arranged before granting the manufacturing license and periodically The Licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority of India may inspect the manufacturing premises of manufacturing units outside India on need basis.	Additional information BPOM Regulation No. 7 Year 2019 on the assessment on GMP compliance of imported drug manufacturing facilities. The manufacturer which is first time register export product to Indonesia should provide SITE MASTER FILE (SMF) for GMP evaluation. After evaluation of SMF, BPOM will approve to continue registration process of NDA or request a desktop inspection or request site inspection. Before inspection, the manufacturer should provide Pre-inspection document for preparation of the site inspection. After inspection, BPOM will issue approved or reject to continue registration NDA. The inspection report from other Authorized Health Authority can be consider for Waive of Inspection to the Manufacturer. BPOM do not disclose total amount of inspection in a year. Referring to the BPOM Regulation No. 7 Year 2019 article 13: Point 2 mentioned amounts of BPOM inspector at least 2 person and maximum 4 person each section Point 3. Mention that inspection conducted maximum 3 days for non-sterile products and 4 days for sterile products.	GMP compliance is a pre-requisite for obtaining Product Marketing Approval in Japan (see Pre-approval inspection, GMP). GMP inspection of a licensed manufacturer is performed every five years either as an on-site inspection or by inspecting the documents.	Pre-approval GMP assessments basically are conducted by desk-top assessment by reviewing the GMP documents that are listed in the regulation. If necessary, on-site inspection will be conducted under following conditions: 1) Manufacturing site that has no history of inspection conducted by MFDS or where waived inspection period has passed 2) Sites with any significant reason for conducting inspection during desk-to assessment (e.g. Manufacturing sites with critical GMP non-compliances, significant changes in facilities compared to the previous inspection, necessity of inspection during the approval and review process, and request of an applicant on on-site inspection) After the GMP inspection, the domestic manufacture is given GMP certificate according to the dosage forms that MFDS have found to be GMP compliant. The expiration date of the GMP certificate is usually 3 years, but the date could be shortened based on risk-based plans. For foreign manufacturers, we also conduct post-approval GMP inspection based on risk-based plans.	Manufacturers are subject to GMP conformity assessments through acceptable GMP evidence or GMP inspection. GMP certification are accepted from PIC/S or ASEAN MRA countries.	GMP clearance for foreign manufacturers is obtained either through desktop review (if PIC/S-GMP certified manufacturer), or through on-site inspection (for non-PIC/S) For locally manufactured products, GMP certificate is issued through actual inspection. (Administrative Order No. 2013-0022)	Domestic manufacturers in Singapore are subjected to licensing and periodic GMP audits by HSA. All new overseas manufacturers will be subjected to a GMP Conformity Assessment by HSA. Refer to: GMP CONFORMITY ASSESSMENT OF AN OVERSEAS MANUFACTURER, July 2020	Measures for the Management of Changes in Foreign Manufacturers of Imported Pharmaceuticals (Version 3) was announced on Nov. 16th, 2022. The major changes include adding change application of Foreign Manufacturers of Imported Pharmaceuticals and list of major changes as attachment. https://www.fda.gov.tw/TC/siteListContent.aspx?sid=301&id=7454&chk=90101064-23aa-44e7-866f-59dae39361be	GMP accreditation was replaced by GMP clearance. On-site inspection required if document verification insufficient. Require GMP clearance for all manufacturing flow in P3 except Quality testing site. Site inspection might be required in case submitted document is insufficient.	**GMP evaluation process** (Art. 7 of Circular 35 revised by Circular 12/2022/TT-BYT) 1. Documents used in assessing the satisfaction of GMP principles and standards: The WHO - GMP principles and standards documents or the GMP principles and standards documents specified in Clauses 2, 3, 4, 5 and 6 Article 4 of this Circular correspond to the production activities of the manufacturer. 2.Manufacturing establishment presents summary of organization, personnel and activities applying for GMP 3.Evaluation team conducts GMP assessment at the production facility. In cases where an establishment performs one or several stages of the production process, the evaluation content shall cover only the requirements corresponding to one or several production stages performed by the establishment; 4.Evaluation team meeting with manufacturing establishment to inform about any pending items 5.Evaluation team prepare and sign the evaluation form, to also be signed by manufacturing establishment 6.Complete the Evaluation Report.

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Manu -facturing	GMP system Please describe frequency/number of on-site inspections to domestic/overseas manufacturers by the authorities.	Since Nov. 2019, CFDI newly established a column on its website to notice the list of drug registration applications received from CDE, to which CDE required research on-site inspections and manufacturing on-site inspections	Since the manufacture license valid for only 1 year, inspection will be made at least on annual basis for the concerned manufacturers.	Annually for domestic manufacturers by State FDA and in some cases joint inspection by State and CDSCO. For overseas manufacturers, CDSCO has provision to inspect the sites on case to case basis.	No publish information	In FY2019, there were 1,891 GMP inspections (324 in Japan and 1,567 overseas), and 158 (46 in Japan and 112 overseas) were conducted on-site. About 87% of overseas field were in the Asian region.	[Frequency] routine inspection: every 3 years, but could be changed based on risk-based plans. [Number of on-site inspections] There is no official information - Due to COVID-19, overseas on-site inspection has not been conducted for the past 2 years but since May 2022, it has resumed for the place where visits are available depending on the quarantine situation of each country.	Number of GMP Inspections in 2021 was 369 (NPRA Annual Reports)	For local manufacturers, inspection is required prior to opening, with follow-up inspection within the validity of the issued license (three years). For foreign manufacturers, inspection prior to product registration is mandatory for non-PIC/S certified manufacturers. Follow-up inspection may be conducted but is not mandatory for renewal of GMP certificate. (Administrative Order No. 2013-0022 and FDA Circular No. 2014-016)	No data	The supporting measures on oversea inspection for COVID-19 pandemic was announced on Sep. 26th, 2020. For the oversea inspections already arranged in 2020 and 2021, TFDA would evaluate whether to adopt the paper review in a case by case basis. Please refer to TFDA website(https://www.fda.gov.tw/TC/lawContent.aspx?cid=68&scid=180&id=3288)	Depend on risk assessment and management (frequency can be 1 or 2 or 3 years)	GMP periodic inspection every 3 years (not including ad-hoc inspections by MoH, DOH) (Source: Article 9, Circular 35/2018/TT-BYT)
	DMF system Please describe DMF system (or plan for introduction). Is DMF mandatory or optional?	Manufacturers of chemical APIs, excipients and primary packaging materials and containers shall register product information and research data on the registry platform. When a drug product applicant submits the drug registration application, the chemical APIs, excipients and primary packaging materials and containers having been registered can be directly selected; where chemical APIs, excipients and primary packaging materials and containers having not been registered are selected, related study data shall be submitted together with the drug registration application.	Not specified.	No DMF system exists. (Note: CMC part of application dossier is called DMF, but it does not mean DMF system as in other countries.) API DMF as per ICH CTD is also acceptable.	DMF (open & closed part) of API are needed as mandatory for generic and NCE API.	The submission of Master File (MF) is optional. Drug substance, Intermediate, New excipient, Packaging material etc. are components of the MF.	DMF system is mandatory for the following drugs: - drug substance of a new drug product - drug substances announced by the MFDS - drug substances derived from human placenta - drug substances for injection [Excludes] - orphan drugs - Biologics, Advanced biopharmaceutical drugs - radiopharmaceuticals - export-only drugs - pharmacologically inactive ingredients (excipients, additives, etc.) - Ingredients that fall under the drug shortage prevention drugs classification, and drug substances aimed at providing nutrients (e.g. glucose, amino acids, fatty acids, vitamins, minerals, etc.)	A DMF is required for API registration and may be replaced by a CEP or full details of Part II S ACTD.	With the adoption of the ASEAN CTD, maintenance of DMF is mandatory but not required for submission.	DMF is optional, if a Drug Master File is submitted, then a separate declaration letter issued by the applicant must also be provided to state that the DMF submitted to HSA is identical to that submitted to the chosen reference drug regulatory agency. APPENDIX 11 GUIDELINE ON DRUG MASTER FILE (DMF) (Aug 2021)	Drug substance DMF is mandatory for NDA approval. DMF dossier can be reviewed during NDA review process or applied as a separated application. DMF is required for replacing or alternative sites of drug substance.	DMF is optional.	N/A
	DMF system Annual or periodical update reporting required?	Yes NMPA is establishing the system of annual report. According to new DRR, (1) Minor changes in drug manufacturing process; (2) Other changes subject to reporting as specified by the NMPA shall be included by MAH in annual report. Besides, NMPA issued an exposure draft of Annual Report Administration Regulation and Template for public comments.	Not specified.	N/A	No. Update will be as one requirement on certain registration variation (e.g. MA Transfer, etc.)	ICH Q12 was issued in Oct, 2021	Yes DMF change management is divided into major changes and minor changes according to the level of change compared with the previously registered DMF. In case of major changes, documents shall be reviewed after the change registration, and minor changes are processed as change report (annual report).	No (Changes are to be submitted as post-approval variation applications.)	Maintenance/updating of DMF is mandatory but not required for submission.	Yes DMF holders and applicants are responsible for maintaining and updating the DMF. When a DMF has been updated, the table of summary of changes and the DMF Submission Form must be provided together with the updated sections of the DMF. If there are changes to the DMF that will result in a post-approval variation to the drug product, product registrants must file a post-approval variation (see Chapter F Post-Approval Process). APPENDIX 11 GUIDELINE ON DRUG MASTER FILE (DMF)(Apr 2022)	There is no annual update reporting in Taiwan. However, DMF approval is valid for 5 years and combined with NDA drug license. Once the change including major or minor change, it should be filed to TFDA, the detail post-approval major/ minor change classification, please refer to appendix 12 of “Drug Review and Registration Guidance.”	No Not required	No N/A for imported products.

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Manu -facturing	Contents of packaging label and language	The required contents are described in CFDA order 24, Regulation on Drug Insert Sheet and Label. According to Announcement of the NMPA on Relevant Matters for Implementation of the Drug Registration Regulation (No. 46 of 2020), MAH should update the Package Insert and label in accordance with new DRR Article 123 since Dec. 1st. The contents should be written in Chinese	English or English and Chinese, requirements described in Guidelines on the Labeling of Pharmaceutical Products.	The manners of labelling of new drugs for the purpose of clinical trial, BA/BE Study are described in rule 66 & 73 of Chapters VIII and IX respectively of the NDCT, 2019. Package Insert and packaging labels should be written in English. The labeling requirements for primary and secondary and all labels are outlined in Rules 96 and 97 of Drugs Rules 1945	Annex X and XI, Drug Registration Guideline No. 24 Year 2017 on minimum information that must be stated in the product information and packaging materials.	According to the enforcement of the revised PMD Act in August 2021, the package inserts have been digitized, and the provision of information on paper included in the products has been abolished in principle.	The contents of each labeling type are described according to the following regulations. 1) Drugs (1) Container · Article 56 of the "Pharmaceutical Affairs Act" · Article 69 of the "Regulation on Safety of Medicines, etc." (2) Carton (outer package) · Article 57 of the "Pharmaceutical Affairs Act" · Article 69 of the "Regulation on Safety of Medicines, etc." (3) Package leaflet · Article 58 of the Pharmaceutical Affairs Act" · Article 70 of the "Regulation on Safety of Medicines, etc." 2) Quasi-drugs · Article 56 of the "Pharmaceutical Affairs Act" · Article 74 of the "Regulation on Safety of Medicines, etc."	Details given in the DRGD. The labeling for pharmaceutical products are in English or Bahasa Melayu. Some labelling statements are mandatory in Bahasa Melayu. Some country specific requirements include declaration of ingredient derived from animal origin (active and excipient) including starting materials and gelatine (e,g., porcine, bovine), name and content of alcohol, where present and Controlled Medicine..	The required contents are described in Guidelines on the Labelling of Pharmaceutical Products. The contents should be written in English and/or Filipino. (Administrative Order No. 2016-0008)	Refer to: GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE APPENDIX 7 Points to Consider for Singapore Labelling, Apr 2021. The product labels, PI and/or PIL must be in English. If non-English text is included in the labelling, applicants must provide an official statement to declare that the non-English text is complete, accurate and unbiased information and is consistent with the English text. Information provided in the labels should be consistent with the information submitted in the application dossier. Any discrepancies should be highlighted and brought to HSA's attention. Registrants of Therapeutic Products (TP) who have a secure online system may distribute the HSA-approved PI and/or PIL in the form of an e-PI/PIL. The e-PI/PIL may be distributed with or without physical printed copies contained in the products. APPENDIX 7A GUIDANCE ON ELECTRONIC LABELLING FOR THERAPEUTIC PRODUCTS, Apr 2021.	The requirement is described in Article 20 of "Regulations for Registration of Medicinal Products." The contents of outer box should be both in English and Chinese. Chinese packaging insert is mandatory while English PI is optional. Any local redressing activities need CMO registration to the drug license and showed CMO information in the package insert	Follow ASEAN labeling requirements Thai language required for - category of drug - expiration date - special warning package leaflet in Thai.	Vietnamese. The currently valid Circular on Labelling no. 01/2018/TT-BYT issued by the Ministry of Health which is going through the revision process: Outer package labels (Article 7) For drugs, drug raw materials: 1.1 The outer packaging label of a drug must show the following contents: a) Drug name; b) Dosage form; c) Composition, strength, weight or concentration of pharmaceutical substances, medicinal materials in the drug formulation; d) Packaging size; d) Indications, method of administration, contraindications; e) Number of certificates of marketing authorization or the number of import license (if applicable); g) Batch number, manufacturing date, expiry date, DP's specification, storage conditions; h) Warnings and precautions; i) Name, address of DP's manufacturer; k) Name, address of importer (in the case of imported drugs); l) Origin of the drug. 2. The outer packaging label of a drug raw material (including medicinal materials, traditional medicinal semi-finished medicinal materials, semi-finished drugs) must show the following contents: a) Name of the drug raw material; b) Weight or volume of the drug raw material in the smallest package unit; c) Quality specification of the drug raw material; d) Number of certificates of marketing authorization or number of import license (if applicable); d) Batch number, manufacturing date, expiry date, storage conditions of the drug raw material; e) Name, address of manufacturer; g) Name, address of importer (in the case of imported drug raw materials); h) Origin of the drug raw material. 3. Labels of controlled drug raw materials (including semi-finished drugs): Apart from the contents stipulated under clause 2 of this Article, raw materials being pharmaceuticals, medicinal material or semi-finished drugs containing pharmaceutical substances, medicinal materials belonging to the List of narcotic, psychotropic substances, drug precursors, hazardous drug raw materials, hazardous medicinal materials, radioactive drug raw materials, must have outer packaging printed with the wording "Narcotic raw materials", "Psychotropic raw materials", "Drug precursor raw materials", " Hazardous raw materials", "Hazardous medicinal materials "," Radioactive materials" respectively. The wording "Narcotic raw materials", "Psychotropic raw materials", "Drug precursor raw materials", " Hazardous raw materials", "Hazardous medicinal materials ","Radioactive materials" must be printed in Bold in a textbox and on the label's facesheet bearing the name of the drug raw materials. 4. Where the contents stipulated in clause 1 of this Article cannot be fitted into the outer packaging label, the contents stipulated in point đ clause 1 of this Article may be summarily presented as follows: indications, contraindications and other information: see enclosed package insert". Secondary packaging labels (Article 8) 1. The secondary packaging label must show at a minimum the following contents: a) Name of the drug; b) Batch number; c) Expiry date. 2. In cases where the secondary packaging is made of a transparent material that allows for information on the primary packaging label to be seen through, such secondary packaging does not have to be printed with the contents stipulated in clause 1 of this Article. Primary packaging labels of drugs, drug raw materials (Article 9) 1. Labels of drug primary packaging must show all the following mandatory contents: a) Drug name; b) The quantitative composition, strength, concentration or volume of pharmaceutical substances, medicinal materials in the drug formulation; c) Batch number; d) Expiry date; đ) Name of manufacturer. 2. Labels of primary packaging of drug raw materials With regard to drug raw materials that have an outer packaging showing all the contents stipulated in clause 2 and clause 3 Article, unless they are removed from the outer packaging for retailing, labelling on the drug primary packaging shall not be required. 3. With regard to drugs, drug raw materials having no outer packaging, the contents stipulated for outer packaging labels under Article 7 of this Circular must be printed in full on the primary packaging. Format of supplementary labeling (Article 10) 1. Supplementary labels must show all the mandatory contents in Vietnamese language that are not yet available or still missing from the original label in accordance with the provisions of Article 7 of this Circular. 2. Where the size of supplementary labels is too small to fit all the mandatory contents stipulated under clause 1 of this Article, some of such contents shall be presented as follows: a) Indications, method of administration, contraindications and other information: see enclosed package insert; b) Cross reference of manufacturing date, expiry date, batch number that are presented on the original label; c) Number of certificates of marketing registration or number of import license: may be left blank but number of certificates of marketing registration or import license (if applicable) must be filled in before placing the drug on the market.

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Manu-facturing	Bar code on packaging materials	NMPA published Announcement of the National Medical Products Administration on the Building of the Information Traceability System for Key Products (No. 111, 2020), MAH shall implement the main responsibility of drug quality management in the whole process, establish an information traceability system, and collect the traceability information throughout the process. By December 31, 2020, the traceability of key products such as the selected products in volume-based procurement, narcotic drugs, psychotropic drugs, and blood products should be basically achieved. NMPA issued Printing Specification for Drug Traceability Identification (Exposure Draft) and Public Query Results of Drug traceability code Display Specification (Exposure Draft) on Jun. 21 for public comments. Additionally, NMPA published Identification Specification of Drug Traceability Code and Display Specification for Consumer Query Results of Drug traceability (No.50, 2020) on Jun.23, 2022.	Not required for product registration.	For product registration, no concern. For supply to government hospital: GTIN barcode is required Barcode requirements using GS1 identification standards has been implemented for exported products. (Reference: The Office Memorandum No: Z-16025/02/08-EPW dated 6th May 2011 by MoHFW). For local Indian market, it is still not made mandatory ●Barcoding is made mandatory for top 300 drugs in India for track and trace purposes effective 01-Aug-23 (reference: Drugs (Eighth Amendment) Rules, 2022published through GSR 823(E) dated 17-11-2022) - will come into force from Aug. 1, 2023. ●Barcoding is mandatory for all APIs manufactured or imported in India to bear QR code with 11 data points (reference: GSR 20 (E) dated January 18, 2022 – have become effective from Jan.1, 2023.	New Regulation BPOM Regulation No. 22 Year 2022 regarding 2D Barcode, enacted on Oct 5, 2022. Authentication must be implemented no later than 4 years after the first electronic MA certificate is issued. Identification must be implemented no later than 12 months after the electronic MA certificate is issued since this regulation is enacted. There are grace period for authentication until Dec 7, 2027 (prescription drug including biological product, narcotics, psychotropic) and Dec 7, 2025.(Drugs included in the class of over-the-counter drugs and Limited over-the-counter drugs, herbal medicine, quasi drug, health supplement, cosmetic food) There are grace period for identification until Dec 7, 2023. The grace period for both primary and secondary packaging. The regulation for drug, food, herbal medicine, cosmetic & health supplement.	Yes Bar Code display including information such as expiration date, serial number or serial number and product code.	Yes Barcode or electronic tag (RFID tag) should be indicated on every drugs(manufactured or imported.)(excludes medical gas, API that are manufactured only for the purpose of manufacturing its own drug product, medicinal herbs, medicine for clinical trials)	No Bar code is optional.	Bar code requirement (GPIN) is voluntary. However, there is an initiative from the government to start pursuing track and trace, starting with barcoding. (FDA Circular No. 2016-011)	No No regulatory requirement on bar code. It is an internal company logistics requirement.	OTC products should be printed QR code in the outer box by Dec 31st 2019. TFDA launched E-labeling pilot program on 30th Dec 2021 for prescription medication for two years starting from 1st Jan 2022.(https://www.fda.gov.tw/TC/siteListContent.aspx?sid=9354&id=39614)	No No regulatory requirement for Bar code But some hospitals require barcode	Yes, but follow the roadmap regulated by MoH. The label of the drug's, the drug's raw material outer packaging must be printed with a bar code or a QR (quick response) code or a Data Matrix Code (DMC): but the road map to implement this requirement has not been issued. (Clause 13 b) Article 22, and Clause 1 l), Article 48, Circular 08/2022/TT-BYT)

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		RDPAC/PhIRDA	HKAPI	OPPI	IPMG	JPMA	KPBMA/KRPIA	PhAMA	PHAP	SAPI	IRPMA	PReMA	PG
Post approval	Renewal system of approved license	Renewal is required every 5 years, and should be submitted by MAH no less than 6 months before expiration date of approval license.	Renewal required every 5 years.	Renewal system has been implemented for the followings. 1) Import license (Every 3 years. Renewal application should be made 3 months before the expiry of the existing license.) 2) Registration certificate (Every 3 years. Renewal application should be made 9 months before the expiry of the existing license.) 3) Manufacturing license – perpetual subject to payment of retention fee every 5 years. The license will be expired if the renewal applications not made within six months of its expiry) Marketing Authorization is one time issue, no renewal required.	Renewal required every 5 years	Not renewal, but a re-examination system is adopted. Drug monitoring is required for 8 years for NCE drug, 4-6 years for new indication/ administration route and 10 years for orphan drug.	Yes. Renewal should be applied to MFDS, and below documents should be submitted in every 5 years. (for orphan drug: 10 years). 1. Data concerning safety management collected during the Effective Period and action plan a. Data pertaining to the expedited report defined in Annex 4-3 “Post marketing safety management practices for drug products” (including adverse event and adverse drug reaction data provided from Korea Institute of Drug Safety and Risk Management (hereafter “KIDS”) according to the subparagraph 2 and 6 of the Annex 4-3 of the Regulation) b. Data pertaining to the periodic data defined in Annex 4-3 “Post marketing safety management practices for drug products” (including adverse event and adverse drug reaction data provided from KIDS according to the subparagraph 2 and 6 of the Annex 4-3 of the Regulation) c. Analysis and evaluation (including summary) for the data specified in the items a and b and safety management measures prepared by a person responsible for safety control. d. If there are no reports submitted pursuant to items a and b, No. 4 standard operating procedures (SOPs) in the Annex 4-3 post marketing safety management practices for drug products shall be submitted. 2. Data concerning the state of use in foreign countries and the safety-related measures a. Data on the usage status of each country collected during the Effective Period, and data that can confirm the latest approved matters such as the date of approval, ingredients and contents, indication and usage, dosage and administration, etc. 3. Quality management data collected during the "Effective Period" a. Data falling under „7.3 Product Quality Review” stated in Annex 1 Good Manufacturing Practices(GMP) for pharmaceuticals b. A copy of the effective Certificate of Compliance for each pharmaceutical issued under the provision of Article 48.2 of the Enforcement Regulation (for imported drugs, a copy of the effective manufacturing certificate issued by the production country's government or public institution) 4. Matters pertaining to labeling a. Effective container · packaging and attached documents at the time of Renewal Application under Articles 56 to 58 of the Act b. Data pertaining to the labeling change history stated in Subparagraph 12 of Annex 1 Good Manufacturing Practices (GMP) for pharmaceuticals 5. Data pertaining to actual result of manufacture · import during the Effective Period a. Data of annual manufacture · import results (including results sorted by manufacturing site and packaging unit) under Article 38.2 of the Act and Article 2 and 3 of the “Regulation on Reporting Manufacture, Export, and Import of Medicinal Products” b. Supportive data to confirm the exceptional conditions, for pharmaceuticals falling under Article 21 of the Enforcement Regulation or Article 3.4 of this Regulation 6. Effective certificate of approval or notification of pharmaceutical manufacturing, marketing and import * Above, Annex means the annex of “Regulation on Safety of Pharmaceuticals, etc.”.	Renewal required every 5 years. Renewal needs to be submitted 6 months prior to registration expiry. A conditional registration is valid for two years. Thereafter, the conditional registration may be renewed 2 times. For products approved via Conditional Registration During Disaster pathway, the conditional registration is valid for 1 year and can be renewed up to maximum of 2 times.	Renewal required every 5 years. (Bureau Circular No. 5 s. 1997)	Reference to “RETENTION OF THERAPEUTIC PRODUCT ON THE PRODUCT REGISTER TPB-GN-002-002”. All registered therapeutic products will remain on the Register, unless: a) The registration is suspended or cancelled by HSA, or b) The registration is cancelled upon application by the registrant, or c) The registrant has failed to make a payment for an annual retention fee within 60 calendar days after the retention fee due date.	Renewal required for approved license every 5 years. On-line renewal procedure (e-submission) is mandatory from 1st Jul 2020. According to the amendment of “Regulations for Registration of Medicinal Products” announced on 14th Sep 2021, the post-approval letter of the specifications and testing methods based on the latest edition of pharmacopoeia or the manufacturer’s specifications should be provided. If the specifications are not changed, the assessment statement should be provided.	Company license: There are 3 kinds of license in Thailand which are Manufacturing license, Import license and Sale license (wholesale or retail), all of which require annual renewal. Based on new Thai Drug Act 2019, the certificate of drug formula registration shall be valid for seven years from the date it was issued. Product license will be automatically withdrawn if no production/importation every 2 consecutive years. The drug classified as narcotics and psychotropics shall subject to renewal every 5 years.	(Art. 8 Circular 08/2022/TT-BYT) 1. The validity period of certificate of marketing registration of drugs, drug raw materials, is 05 (five) years from issue date or renewal date, except for the categories stipulated in clause 2 of this Article. 2. The validity period of certificate of marketing registration of the following drugs is 03 (three) years from issue date: a) New drugs, vaccines for the first time issued with certificate of registration for marketing in Vietnam; b) Drugs having the same drug substance, concentration, strength, dosage form with those of a new drug for which a 5 (five) year-validity certificate of marketing registration has not been issued; c) Drugs for which ongoing monitoring for safety [and] effectiveness is recommended by the Council. d) Drugs of the categories stipulated in point a, b and c of this clause but at the point of dossier submission for certificate renewal the report on the drug safety, effectiveness is not yet available as the drugs have not been marketed or such report is already available but in the Council’s opinion, the volume of the drugs being consumed, the number of patients the drugs were used on, the usage duration are still limited or of which ongoing monitoring for safety [and] effectiveness are recommended by medical service establishments. 3. Each drug product, drug raw material covered by a registration marketing certificate shall be uniquely identified by an ID number according the standard format stipulated in Annex VI of this Circular. 4. Timeline for submission of renewal application dossiers: Within 12 months before the expiry date of a Certificate of marketing registration, the registrant must apply for certificate renewal. 5. Where there is a change in administrative document as part of the renewal dossier, after 12 months from the date of issuance of the Decision for Certificate renewal, the registrant must effectuate the changes as approved in the renewal dossier. 6. Quantity of marketing registration certificate issued to drug products of a same manufacturer with the same drug substance or medicinal material composition; dosage form; route of administration; strength or concentration in a unit dose: 01 certificate for the drug product bearing the trade name and 01 certificate for the drug product under international non-proprietary name. This provision shall not apply to the drugs produced as part of contract manufacturing arrangements or drug products produced solely for export purposes.

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Post approval	Post marketing surveillance or safety monitoring program	Yes MAHs shall proactively carry out post-marketing studies to further verify the safety, efficacy and quality controllability of drugs and enhance ongoing management of marketed drugs. Where the drug approval license and its attachments require the MAH to carry out related post-marketing studies, the MAH shall complete the studies within the prescribed timeline and submit a supplementary application, notification or report as required. After a drug is marketed after approval, the MAH shall continue to carry out the drug safety and efficacy studies, timely file notification or submit supplementary applications for revision of the package inserts according to the relevant data, and constantly update and improve the package inserts and labels. The drug regulatory authorities may require the MAH to revise the package inserts and labels according to the adverse drug reaction monitoring and post-marketing review results. Additionally, NMPA revised and issued the Provisions on the Administration of Drug Recalls on Oct. 26, effective on Nov 1, 2022. NMPA issued Administrative Provisions on Annual Reports for Drugs on Apr.12, 2022. The cut-off date for filling the 2021 annual report information is Aug 31, 2022; from next year onwards, the annual report information of the previous year shall be filled in before Apr 30 the next year.	For NCE and biosimilar. PSUR has to be submitted every 6-monthly for the first 2 years of product registration approval, and annually in the following 3 years.	PSUR submission is mandatory for a period of four years. For new drug, every 6 months for the first 2 years, and annually for another 2 years. May be extended by the authority in the interest of public health. (Reference: Fifth Schedule of NDCT 2019) PSURs due for a period must be submitted within 30 calendar days of the last reporting period	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 5-12 and Article 14. PSUR/PBRER submission is required for marketed drug with new safety issue and need to monitor the safety aspect based on the assessment, new drug, biological product including biosimilar, certain generic drug and changes in drug that can increase a safety risk. PSUR/PBRER need to be submitted every 6 months for the initial 2 years, and every year for 3 years later. There is an obligation to report all Adverse Events (unexpected/expected, serious/ non-serious) in Indonesia and literature report from Indonesia and international to BPOM. There is signal management process and reporting.	Yes According to the ICH E2C(R2) guidelines, PSUR has been changed to PBRER. PBRER submission is mandatory every 6 months in the first two years and annually after two years. Use-result survey data should be included in the submission.	Yes According to Annex 4-3 of the "Regulation on the Safety of the Medicinal Products, etc". , it is mandatory for the MAH to conduct Post marketing surveillance program and report to the MFDS regularly.	Yes PSUR/PBRER is mandatory for NME: every 6 months in the first 2 years, and annually for the subsequent 3 years. Other safety monitoring programs may be requested if deemed necessary.	An RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Reference to: GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, 1 Mar 2021 This guidance addresses the types of documents to be submitted at the point of application for product registration, and during the post-marketing phase of the therapeutic products and CTGTP (e.g. during variation application review or when new significant safety issues are identified). The requirements and timelines for reporting safety information related to therapeutic products and CTGTP are also included. The topics covered in this guidance include the following: ▪ Records of adverse events (AE); ▪ Serious AE reporting; ▪ Risk management plans (RMP); ▪ Periodic benefit-risk evaluation reports (PBRER); ▪ Updates on actions taken by other regulatory authority or company in response to safety issues.	Yes Pharmacovigilance period is first 5 years for NCE drugs. PSUR should be submitted every 6 months in the first 2 years and annually for the rest 3 years. PSUR/PBRER submission period can be adjusted based on global international birthday (IBD) and its data lock point (DLP) within 3 months of drug license collection.	Yes Active pharmacovigilance for early approval drugs for example clinical phase II registration, SMP will be classified by risk level of drugs. Monitoring period depends on risk level (as FDA announcement on 28 Apr 2017). RMP are required.	(Art.5, Circular 08/2022/TT-BYT) 1. Pharmaceutical business establishments, medical service establishments shall monitor, supervise, collect, synthetize, evaluate information and send reports to the competent authority of cases of adverse reactions following vaccination, drug adverse reactions in accordance with the provisions of Article 77, Article 78 of Pharmaceutical law, national guidance on pharmacovigilance issued by Ministry of Health and applicable regulations. 2. The registrant shall report on the surveillance and assessment of safety [and] effectiveness of the drugs it registered in accordance with the provision of clause 2 Article 8 of this Circular using Form 2A/TT (for drugs) or Form 2B/TT (for vaccines): a) To DI&ADR National Centre every 6 months throughout the marketing registration's validity period; b) To Drug Administration upon the submission of application for renewal of marketing registration certificate; 3) Drug-consuming medical service establishments shall report on the consumption of the drugs stipulated in clause 2 Article 8 of this Circular using Form 2C/TT issued with this Circular every 6 months throughout the marketing registration's validity period and send the report to DI&ADR National Centre. 4) The DI&ADR National Central shall be responsible to synthesize, evaluate and send the reports to Drug Administration every 6 months.

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Post approval	Risk Management Plan (RMP)	-Adopt to ICH E2E for the NDA submitted after Feb. 12th 2020 and the NDA approved after May. 12th 2020. -For the initial NDA or BLA of oncology drug in China, RMP should be submitted to CDE together with NDA/BLA. When NDA/BLA approved, MAH should strictly implement the pharmacovigilance plan and risk minimization measures specified in the RMP. -RMP is required the periodical review and updates, which initial review will be 2 years after drug launching. When 5-year renewal of license, MAH also needs to report the implementation status of RMP. CDE has issued Editing Guideline on Clinical Risk Management Plan (Trial Implementation) on Jan.6, 2022, effective since the issuance day.	Required for NCE and biosimilar registrations.	Risk Management Plan to be part of the Periodic Safety Update Report (PSUR), wherein the license holder will provide the brief details of safety concern and necessary action taken by him to mitigate these safety concerns. Separate RMP is not asked for	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 4, 13 and Annex II. RMP submission is required for new drug, biological product including biosimilar, certain generic drug and changes in drug that can increase a safety risk. As part of registration dossier (Administrative Document). RMP could be in Bahasa or English. RMP format could refer to global RMP.	RMP document is mandated for NDA as CTD M1.11.	RMP is mandatory for new drugs, stem cell therapeutics, orphan drugs, Advanced biopharmaceutical drugs, drugs for which the Minister of the MFDS deems it necessary to submit risk management plans due to occurrence of serious side effects following marketing (e.g. valproic acid, isotretinoin, alitretinoin-contained drugs, etc.) and drugs that are designated for PMS. The detailed items to be included in RMP is specified in the Annex 6-2 of the “Regulation for Approval, Notification and Review for Drugs ”, Annex 9-2 of the “Regulation of Approval and Review of Biologics” and Annex 5 of the “Regulation of Approval and Review of Advanced Biopharmaceutical drugs” * The re-evaluation system, which has been in effect since 1995, is a system that re-evaluates the safety and efficacy of new drugs and drugs determined by the minister of MFDS by investigating adverse event that did not appear in the approval process. The system overlaps with the RMP introduced in 2015, which have led problems such as duplicate submissions of data. The MFDS announced that the re-evaluation system will be deleted from 2023 and integrated into RMP. With the deletion of the re-evaluation system, a new system will be established to set the period for drug data protection.	Yes RMP document is required for New Drug Products/ Biologics, and in certain cases, new indications. A new RMP or an update, as applicable, may need to be submitted at any time during a product’s life-cycle. (Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders 1st Edition August 2021)	RMP is required for submission of NDAs. There's no local format of RMP, but FDA recommends compliance to EU format. FDA requires the creation of a Philippine-specific RMP, detailing specific RMP activities for the Philippines. FDA also requires an RMP for the establishment. Manufacturers are required to submit this as part of LTO applications; other establishments need not to submit this but are part of inspection requirements. (FDA Circular No. 2018-013, FDA Circular No. 2020-003, Administrative Order No. 2020-0017)	RMP requirements explained in Section 6 (page 16) of GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, 1 Mar 2021 All new drug applications type 1 (NDA-1) and biosimilar applications must have an accompanying RMP submitted. For other application types such as NDA-2 or 3, major variation application (MAV) or generic drug application (GDA), RMP documents may be requested by HSA on a case-by-case basis: (i) For NDA-2, the request for RMPs may be in response to a new safety concern arising from a new route of administration; (ii) For MAV, the request may arise as a result of a new safety concern associated with a new indication that may require additional PV activities and/or RMAs; (iii) For GDA, an RMP may be required if the innovator or reference therapeutic product has safety concerns that have been identified to require additional local PV activities and/or RMAs.	The necessary of local RMP will be decided by TFDA during the NDA review. RMP protocol will be discussed and finalized between TFDA and NDA applicants.	The guideline on RMP for all products announced by FDA for new drugs.	RMP is required only to submit in the application for vaccine registration. Otherwise not a mandatory requirement. (Art. 23, Circular 08/2022/TT-BYT)_ The request could be given following the decision of Advisory Council for the Grant of Drug Registration License. Risk management plan for a drug should include the following information (Form 7, : - Overview of drugs - Safety information - Pharmacovigilance Plan - Plan of Post-marketing studies - Risk minimization activities - Summary of the plan

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Post approval	Adverse drug reaction (ADR) reporting after marketing	According to NMPA Announcement on Direct Report of Adverse Drug Reaction (2018 No.66), MAHs are required to submit the annual summary report of adverse drug reaction monitoring of the last year prior to March 31 each year. The writing requirements for the annual report will be published on the website of the National Center for ADR Monitoring of China. NMPA also published NMPA Opinions on Further Strengthening the ADR Monitoring and Evaluation System and Capacity Building (2020 No.20).	Serious adverse drug reactions have to be reported as soon as possible and not later than 15 calendar days from date of first receipt	Reference: Fifth Schedule – Post Market Assessment (NDCT Rules, 2019) Serious unexpected adverse reactions: must be reported to the licensing authority (DCGI) within 15 calendar days of initial receipt of the information by the applicant. Serious and Non-serious adverse reactions need to be report to PvPI (Pharmacovigilance program of India) within 15 days and 30 calendar days respectively. Other: to be reported in PSUR	BPOM Regulation No. 15 Year 2022 regarding Pharmacovigilance Implementation Article 5, 6, 10. Reporting is mandated for AE/ADR observed in post-marketing products. 1. Spontaneous serious unexpected in Indonesia, no later than 15 calendar days. 2. Spontaneous non-serious unexpected in Indonesia, report every 6 months. 3. Spontaneous serious expected in Indonesia, no later than 15 calendar days. 4. Serious from Indonesia and international literature, no later than 15 calendar days. 5. Non serious unexpected from Indonesia and international literature, report every 6 months.	Reporting is mandated for ADR observed in the post-marketing products including PMS. Reporting period of Serious ADR is within 15 days (or 30 days for expected ADR).	Reporting is mandated for ADR observed in post-marketing products including PMS. SAE: within 15 days from reported day NSAE: within the first month after every quarter	Reporting is mandated for ADR observed for marketed products. PRHs are required to monitor and report any product safety issues that arise locally or internationally to the NPRA. The timeline for ADR reporting differs by reporter category. (Malaysian Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders 1st Edition August 2021)	ADR reporting is mandatory. (FDA Circular No. 2020-003)	ADR requirements explained in Section 3, 4 and 5 of GUIDANCE FOR INDUSTRY POST-MARKETING VIGILANCE REQUIREMENTS FOR THERAPEUTIC PRODUCTS AND CELL, TISSUE AND GENE THERAPY PRODUCTS, 1 Mar 2021 Upon becoming aware of any serious AE, the company must report the event to the Vigilance and Compliance Branch as soon as possible and no later than 15 calendar days. The initial report of a serious AE should contain as much detail as available but should not be delayed for the sake of gathering more information. The clock for reporting starts as soon as any personnel in the company, including sales representatives, are made aware of the serious AE. If there is uncertainty about whether the serious AE is reportable, the company should still submit a report within 15 calendar days	Reporting is mandated for ADR observed in the post-marketing products. For medical care institutions and pharmacies: 1.Severe ADR cases cause death or life-threatening, the timeline of reporting and forwarding to license holders is 7 days. The required documents should be submitted within 15 days. 2.other SADRs except of death and life-threatening, the timeline is 15 days For license holders, the report in accordance with regulations shall be submitted within 15 days once knowing the SADRs.	Thai FDA announcement on Stipulation of Certification of Registration Application Condition for Adverse Events Reporting of Medicines including Vaccines (dated 5 Feb 2016) 1. The Marketing Authorization Holder to follow up the drug safety and report adverse drug reaction and other drug related problems, including Adverse Events Following Immunization (AEFI) to the Thai FDA, strictly following the drug safety guidelines stipulated by the Thai FDA. 2. The Marketing Authorization Holder to report to the Thai FDA the information and decision condition of the Marketing Authorization Authority in case New Safety Issue is encountered.	Follow Ministry of Health guidance for ADR report. - Patient information (Initials, gender, age/date of birth, weight) - Details of AE* Date of onset/latency, concise description of AE (e.g. type of rash), severity Suspected health products Brand name or active ingredient(s), dosage form, strength, manufacturer, batch number, - Administration route - Concomitant health product - Anamnesis - Reporter's details Name, profession, place of practice, contact no., email address

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Post approval	Variation guideline	For post-marketing changes to drugs, classified management shall be practiced depending on their risks to and the extent of their influence on the safety, efficacy and quality controllability of the drugs. Post-marketing changes are classified into changes subject to approval, notification and reporting. NMPA issued Provisions for Drug Post-approval Change (Trial Implementation) (No.8 2021) on Jan.13, 2021, Technical Guideline on Studies of Post-marketing CMC Changes to Chemical Drugs (For Trial Implementation)(No. 15 2021) on Feb.10, follow by a series of supportive guidelines on variation.	Please refer to the Guidance Notes on Change of Registered Particulars of a Registered Pharmaceutical Product/Substance, issued by the Drug Office, Department of Health of Hong Kong.	Variations are approved in most cases due to lack of clarity of variation class.	Regulation of the Head of National Agency of Drug and Food Control No 24, year 2017 (Annex XVI): Criteria and Procedure of Drug Registration, 1.Major Variation 2.Minor Variation 3.Minor Notification Do and Tell	Yes Partial change application should be submitted for approval of changes. For minor changes, the notification system can be applied. Scope and handling of these changes are stipulated in the PMD Act and several notices.	Yes.(Regulation) "Equivalence Standards for Drugs"	Yes Malaysian Variation Guideline for Pharmaceutical Products (2nd Edition July 2022); Malaysian Variation Guideline for Biologics	Requirements and process is similar to ASEAN Variation Guidelines, with additional country-specific changes and requirements. However, there are plans to establish Philippine-specific variation guidelines. (FDA Circular No. 2014-008, FDA Circular No. 2014-008-A, FDA Circular No. 2016-017)	Yes Reference to GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION IN SINGAPORE TPB-GN-005-010 ; Chapter F Post-Approval Process Aug 2022 Reference to GUIDANCE ON CELL, TISSUE AND GENE THERAPY PRODUCTS REGISTRATION IN SINGAPORE CTGTP-GN-001 - Chapter D Post-Approval Process Feb 2022.	Yes In Pharmaceutical Affairs Act and "Regulations for Registration of Medicinal Products", there are some regulation taken as guideline. In addition, with the amendment of the "Regulations for Registration of Medicinal Products" announced on 28th Sep 2021, variation guideline was been updated.(https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030057) For the e-submission system (EXPRESS) online application for "drug product registration process, license renewal, withdrawal and the post-market administration variation are mandatory to submit by the system from 1st Jul 2020 and related detail announced by TFDA is on the following website: https://e-sub.fda.gov.tw/dohclient/Login.aspx	Yes As per ASEAN Variation Guideline (AVG) and non-AVG WHO guideline for vaccines EU guideline for biologics	Yes The ASEAN Variation Guideline is adopted with few country-specific modifications.
	Post marketing clinical trial as approval requirement	Yes In the case of "conditional-approval", post-marketing clinical trials may be requested.	Not required.	It shall be based on the condition(s) mentioned in New Drug approval letter. Generally, all drugs approved for first time in India are requested to conduct post-marketing surveillance/ a phase 4 trial (as recommended by the Subject Expert committee and DCGI).	No conditional approval in Indonesia. We need to submit completed report for NDA submission	Yes The Authority may request post-marketing clinical trials as an approval requirement if further assessment of efficacy and/or safety is deemed appropriate by the Authority. These requested trial plans are included as a part of the Risk Management Plan (RMP).	No requirement	No Post marketing clinical trial is not a standard approval requirement currently. May be needed for Conditional Registration.	An RMP containing the Pharmacovigilance Plan shall be submitted by applicants, determining whether additional PV activities are necessary. (FDA Circular No. 2021-020, FDA Circular No. 2020-003)	Post-marketing clinical trial may be mandated by HSA as registration requirement, if HSA deem necessary. This requirement may be applicable for the Pandemic Special Access Route as well, source: HSA | Pandemic Special Access Route (PSAR) for Supply of Emergency Therapeutic Products.	Yes	Yes Active pharmacovigilance for early approval drugs for example clinical phase II registration, SMP will be classified by risk level of drugs. Monitoring period will be between 1-2 years depends on risk level. Risk level 1 – active vigilance i.e., cohort event monitoring, patient registry Risk level 2 and 3 – intensified/stimulated reporting	No But Phase 4 can be requested by Advisory Council on issuance of marketing registration certificate for Drugs that have been licensed for marketing but still require further safety [and] efficacy assessment

APAC PMRE TF thanks all the authors & reviewers for their immeasurable contributions to publishing this report and would like to commemorate this great achievement with the names of contributors here.

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